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Psychological therapies for the prevention of migraine in adults (Review)

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[Intervention Review]

Psychological therapies for the prevention of migraine in adults

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ABSTRACT

Background

Migraine is a common neurological problem associated with the highest burden amongst neurological conditions in terms of years lived with disability. Medications can be used as prophylaxis or rescue medicines, but are costly and not always effective. A range of psychological interventions have been developed to manage migraine.

Objectives

The objective was to evaluate the efficacy and adverse events of psychological therapies for the prevention of migraine in adults.

Search methods

We searched CENTRAL, MEDLINE, Embase, PsycINFO and CINAHL from their inception until July 2018, and trials registries in the UK, USA, Australia and New Zealand for randomised controlled trials of any psychological intervention for adults with migraine.

Selection criteria

We included randomised controlled trials (RCTs) of a psychological therapy for people with chronic or episodic migraine, with or without aura. Interventions could be compared to another active treatment (psychological or medical), an attention-placebo (e.g. supportive counselling) or other placebo, routine care, or waiting-list control. We excluded studies where fewer than 15 participants completed each arm.

Data collection and analysis

We extracted study characteristics and outcome data at post-treatment and the longest available follow-up. We analysed intervention versus control comparisons for the primary outcome of migraine frequency. We measured migraine frequency using days with migraines or number of migraine attacks measured in the four weeks after treatment. In addition, we analysed the following secondary outcomes: responder rate (the proportion of participants with a 50% reduction in migraine frequency between the four weeks prior to and the four weeks after treatment); migraine intensity; migraine duration; migraine medication usage; mood; quality of life; migraine-related disability; and proportion of participants reporting adverse events during the treatment. We included these variables, where available, at follow-up, the timing of which varied between the studies. We used the GRADE approach to judge the quality of the evidence.

Main results

We found 21 RCTs including 2482 participants with migraine, and we extracted meta-analytic data from 14 of these studies. The majority of studies recruited participants through advertisements, included participants with migraine according to the International Classification of Headache Disorders (ICHD) criteria and those with and without aura. Most intervention arms were a form of behavioural or cognitive-behavioural therapy. The majority of comparator arms were no treatment, routine care or waiting list. Interventions varied from one 20-minute session to 14 hours of intervention. No study had unequivocally low risk of bias; all had at least one domain at high risk of bias, and 20 had two to five domains at high risk. Reporting of randomisation procedures and allocation concealment were at high or unclear risk of bias. We downgraded the quality of evidence for outcomes to very low, due to very serious limitations in study quality and imprecision. Reporting in trials was poor; we found no preregistrations stipulating the outcomes, or demonstrating equivalent expectations between groups. Few studies reported our outcomes of interest, most only reported outcomes post treatment; follow-up data were sparse.

Post-treatment effects

We found no evidence of an effect of psychological interventions for migraine frequency in number of migraines or days with migraine (standardised mean difference (SMD) −0.02, 95% confidence interval (CI) −0.17 to 0.13; 4 studies, 681 participants; very low-quality evidence).

The responder rate (proportion of participants with migraine frequency reduction of more than 50%) was greater for those who received a psychological intervention compared to control: 101/186 participants (54%) with psychological therapy; 37/152 participants (24%) with control (risk ratio (RR) 2.21, 95% CI 1.63 to 2.98; 4 studies, 338 participants; very low-quality evidence). We found no effect of psychological therapies on migraine intensity (SMD −0.13, 95% CI −0.28 to 0.02; 4 studies, 685 participants). There were no data for migraine duration (hours of migraine per day). There was no effect on migraine medication usage (SMD −0.06, 95% CI −0.35 to 0.24; 2 studies, 483 participants), mood (mean difference (MD) 0.08, 95% CI −0.33 to 0.49; 4 studies, 432 participants), quality of life (SMD −0.02, 95% CI −0.30 to 0.26; 4 studies, 565 participants), or migraine-related disability (SMD −0.67, 95% CI −1.34 to 0.00; 6 studies, 952 participants). The proportion of participants reporting adverse events did not differ between those receiving psychological treatment (9/107; 8%) and control (30/101; 30%) (RR 0.16, 95% CI 0.00 to 7.85; 2 studies, 208 participants). Only two studies reported adverse events and so we were unable to draw any conclusions.

We rated evidence from all studies as very low quality.

Follow-up

Only four studies reported any follow-up data. Follow-ups ranged from four months following intervention to 11 months following intervention. There was no evidence of an effect on any outcomes at follow-up (very low-quality evidence).

Authors' conclusions

This review identified 21 studies of psychological interventions for the management of migraine. We did not find evidence that psychological interventions affected migraine frequency, a result based on four studies of primarily brief treatments. Those who received psychological interventions were twice as likely to be classified as responders in the short term, but this was based on very low-quality evidence and there was no evidence of an effect of psychological intervention compared to control at follow-up. There was no evidence of an effect of psychological interventions on medication usage, mood, migraine-related disability or quality of life. There was no evidence of an effect of psychological interventions on migraine frequency in the short-term or long-term. In terms of adverse events, we were unable to draw conclusions as there was insufficient evidence. High and unclear risk of bias in study design and reporting, small numbers of participants, performance and detection bias meant that we rated all evidence as very low quality. Therefore, we conclude that there is an absence of high-quality evidence to determine whether psychological interventions are effective in managing migraine in adults and we are uncertain whether there is any difference between psychological therapies and controls.

PLAIN LANGUAGE SUMMARY

Psychological therapies for the management of migraine in adults

Bottom line

There was an absence of good-quality evidence that psychological therapy was effective or harmful in managing frequent migraine immediately following treatment or in the longer term.

Background

Migraine is a condition of the nervous system that is common and associated with lower quality of life and disability. Although medications can help manage migraine, they do not work for all individuals and some individuals experience negative side-effects (adverse events). Numerous psychological therapies have been evaluated for the management of migraine in adults. Psychological therapies deliver skills such as education, relaxation, or coping strategies to help adults change their behaviour or thoughts about migraine, to try to reduce their migraine-related symptoms.

Review question

We evaluated psychological interventions for adults with chronic or episodic migraine with and without aura (a warning sign that precedes and predicts a migraine). We compared individuals who received psychological therapy for migraine with a 'control' group. Control groups included usual treatment ('standard care'), or waiting to receive treatment, or receiving another type of intervention such as education. We extracted data on the frequency of migraines (i.e. number of days with migraines, or number of migraines, in the month following treatment) as our primary outcome. We also extracted data on the number of responders (people with a 50% reduction in migraine frequency), migraine intensity, migraine duration (number of hours of migraine per day), migraine medication usage, mood, quality of life, and migraine-related disability. We recorded instances of harm (adverse events) associated with treatment.

Study characteristics

We searched databases in July 2018 and found 21 studies with 2482 participants. Most studies investigated one of three interventions, namely a form of psychological therapy called cognitive-behaviour therapy (CBT), which teaches skills to change thoughts and behaviours. Skills include coping strategies, or biofeedback or relaxation, which teaches people to reduce their tension either by concentrating on relaxing exercises or through a machine that gives feedback about muscle tension or body temperature. The remaining psychological treatments were examined in single studies; they included writing about emotions and eye movement desensitisation, and reprocessing, which uses eye movements to help people accept their pain and other negative experiences. We were interested in outcomes following treatment and at the longest available follow-up.

Key results

We found no evidence that psychological treatments resulted in less migraine frequency in the four weeks following treatment. However, we could only include four studies in this analysis that were not high quality. Four studies reported the proportion of people whose migraines reduced in frequency by 50% or more, and in those studies, people who received psychological treatment were twice as likely to respond to treatment (i.e. 50% reduction in migraine frequency) as those in the control group.

There was no evidence that psychological treatments affected migraine intensity, medication use for migraine, mood or quality of life. Only two studies assessed adverse events, and so we were unable to draw conclusions.

We found very few follow-up data, and no evidence to support or refute any long-term effects of psychological treatment.

Quality of evidence

We rated the quality of the evidence using four levels: very low, low, moderate, or high. High-quality evidence means that we are very confident in the results. Very low-quality evidence means that we are very uncertain about the results. We judged the quality of evidence as very low.

Conclusion

There is no evidence that psychological treatments affect the frequency of migraine. More responders (i.e. those reporting a 50% reduction) received psychological treatment than control, but this was based on very low-quality evidence and therefore we are uncertain of this result. In terms of adverse events, we were unable to draw conclusions as there was insufficient evidence. There were very few long-term data available, and no indication that psychological interventions had any long-term effects. Overall there was an absence of high-quality evidence for the effect of psychological treatment on migraines and therefore we are uncertain whether there is any difference between psychological therapies and controls. Funding of high-quality studies is needed and additional studies may change the conclusions of this review.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Psychological therapies compared with controls for managing migraine in adults: post-treatment outcomes

Psychological therapies compared with controls for managing migraine in adults: post-treatment outcomes

Patient or population: adults (≥ 18 years) with migraine

Settings: clinical and community

Intervention: psychological therapies, post-treatment

Comparison: any control (active, treatment as usual, waiting list)

Outcomes	Probable outcome with control	Probable outcome with intervention	NNTB and/or relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
Migraine frequency (over four weeks) [a] Lower numbers = fewer migraines or fewer days with migraines	Range 2.4 to 9.4 (in individual studies)	The mean migraine frequency in the intervention group was 0.02 fewer migraines or days with migraine than the control group (95% CI −0.17 to 0.13)	Not applicable	681 (4)	⊕⊖⊖⊖ **Very low**[b]	There was no evidence of benefit or harm
Responder rate (achievement of at least 50% reduction in migraine frequency) Higher numbers mean more people responded	240 per 1000	540 per 1000	**NNTB** 3 **RR** 2.21 (95% CI 1.63 to 2.98)	338 (4)	⊕⊖⊖⊖ **Very low**[b]	We observed benefits for responder rate, meaning that people who received treatment were more likely to have a 50% or more reduction in migraine frequency
Migraine intensity [c] Lower numbers = lower migraine intensity	Range 2.0 to 6.7 in individual studies	Mean migraine intensity in the intervention group was 0.13 lower (95% CI −0.28 to 0.02)	Not applicable	685 (4)	⊕⊖⊖⊖ **Very low**[b]	There was no evidence of benefit or harm
Mood [d] Lower numbers = lower reported depression, anxiety and distress symptoms	Range 4.5 to 21.4 in individual studies	The mean mood in the intervention group was 0.08 units higher on the relevant measure (95% CI −0.33 to 0.49)	Not applicable	432 (4)	⊕⊖⊖⊖ **Very low**[b]	There was no evidence of benefit or harm

Migraine-related disability [e] Lower numbers = lower reported migraine-related disability	Range 0.8 to 57 in individual studies	The mean migraine-related disability in the intervention groups was 0.67 lower on relevant measures (95% CI −1.34 to 0.00)	Not applicable	952 (6)	⊕⊖⊖⊖ **Very low**[b]	There was no evidence of benefit or harm.
Adverse events (proportion of people reporting an adverse event) Higher numbers mean more people reporting an adverse event	300 per 1000	80 per 1000	**RR = 0.16** (95% CI 0.00 to 7.85)	208 (2)	⊕⊖⊖⊖ **Very low**[b]	There was insufficient evidence to draw conclusions.

CI: confidence interval; **NNTB:** number needed to treat for an additional beneficial outcome; **RR:** risk ratio

GRADE Working Group grades of evidence

High quality: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate quality: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different.

Low quality: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.

Very low quality: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

[a] Outcome measure: headache diary
[b] Downgraded three times due to very serious limitations to study quality, and sparse data (imprecision)
[c] Outcome measures: headache diary; Migraine Headache Index
[d] Outcome measures: Depression Anxiety and Stress Scales; Hospital Anxiety and Depression Scales; Montgomery-Åsberg Depression Rating Scale
[e] Outcome measures: Migraine Disability Assessment Questionnaire; Migraine Disability Assessment Scale

BACKGROUND

Description of the condition

Migraine is a commonly experienced condition and prevalence is estimated to be between 14% and 16% (Stovner 2007). The Global Burden of Disease study indicated that migraine was the third most prevalent of all medical conditions (Vos 2012), and ranked the burden associated with migraine as the highest of any neurological disorder (Leonardi 2013). The cost of migraine is estimated to be EUR 1222 per person per year, which amounts to an estimated EUR 50 to 111 billion annually across Europe (Linde 2012). Similar estimates from the USA suggest that chronic migraine is associated with costs of USD 1036 per person per year and in Canada with costs of CAD 471 per person per year (Stokes 2011).

The International Headache Society (IHS) defines four types of primary headache: migraine, tension-type headache, trigeminal autonomic cephalgias and other primary headache disorders (IHS 2013; IHS 2018). This Cochrane Review focused on migraine in adults. The two major subtypes of migraine are migraine with and without aura. An aura refers to neurological symptoms that are noticed shortly before the migraine begins. Migraine may also be classified as either chronic or episodic: chronic migraine is distinguished from episodic migraine by headache occurrence on 15 or more days per month for at least three months, with migrainous features on at least eight days per month (IHS 2013).

Migraines without aura

Migraine without aura is an episodic, recurrent condition characterised by a specific set of symptoms and features that distinguish it from other forms of headache (e.g. cluster headache or tension-type headache). Many people experience a mix of migraines with and without aura. IHS criteria are as follows.

At least five attacks that fulfil the following criteria.

- The attacks last four to 72 hours (untreated or unsuccessfully treated).
- Headaches have two of the following four characteristics:
  - unilateral location;
  - pulsating quality;
  - moderate or severe pain intensity;
  - aggravation by or causing avoidance of routine physical activity.
- During headache, one of the two following:
  - nausea or vomiting, or both;
  - photophobia and phonophobia.
- Not better accounted for by another International Classification of Headache Disorders - 3 (ICHD-3) diagnosis (IHS 2013; IHS 2018).

Migraines with aura

In addition to migraines without aura, some people experience migraine with aura, which is characterised by neurological symptoms that typically precede and predict the headache, although for some people these symptoms can continue with the headache. IHS criteria are as follows.

At least two attacks that fulfil the following criteria.

- One or more of the following fully reversible aura symptoms:
  - visual;
  - sensory;
  - speech and language;
  - motor;
  - brainstem;
  - retinal.
- Headaches have at least two of the following four characteristics:
  - at least one aura symptom spreads gradually over five minutes or more, or two or more symptoms that occur in succession, or both;
  - each individual aura symptom lasts for between five and 60 minutes;
  - at least one aura symptom is unilateral;
  - the aura is accompanied or followed within 60 minutes by headache.
- Not better accounted for by another ICHD-3 diagnosis, and transient ischaemic attack has been excluded.

We included participants with migraine with and without aura. We excluded studies of participants who had migraines with atypical aura, including brainstem aura, hemiplegic migraine or retinal migraine.

Description of the intervention

Our review aims to add to the portfolio of Cochrane Reviews that investigate the efficacy of psychological therapies for the management of chronic pain excluding headache (Williams 2012), the efficacy of psychological therapies for the management of chronic neuropathic pain in adults (Eccleston 2015), and remotely-delivered psychological therapies for the management of chronic pain (Eccleston 2014). Most psychological treatments focus on the provision of skills that individuals can use to better cope with their symptoms of migraine. Typically, these skills include a range of cognitive and behavioural strategies aimed at reducing stress, changing interpretations about the migraine experience, or dealing with the symptoms of migraine once they occur. We explicitly excluded therapies that were predominantly physical and did not have sufficient psychotherapeutic content (e.g. yoga). We included psychological interventions regardless of the mode of delivery, for example, whether they were delivered face-to-face or remotely, or whether they were group or individual.

How the intervention might work

In addition to the Description of the intervention above, in the migraine literature, earlier programmes also provided education to avoid triggers of migraine with a view to reducing the frequency, but this approach has been criticised because such avoidance can lead to further sensitisation to those triggers and significantly restrict everyday activities. More recent approaches have included an element of exposure to triggers with a view that people will habituate during the exposure and thereby become less sensitive to their migraine triggers (Martin 2009; Martin 2010).

Why it is important to do this review

Psychological treatments that have the potential to reduce both the personal and economic burden associated with migraine are needed. Although there have been previous meta-analytic reviews

of behavioural treatments, most have included all types of study designs (e.g. before and after studies, randomised controlled trials (RCTs)), which has led to a possible overestimation of the treatment effect (Rains 2005). The only meta-analysis that included only RCTs was prepared on behalf of the Agency for Health Care Policy in 1999 (Goslin 1999), and therefore it is important to have an up-to-date synthesis of evidence. This review aimed to fill that gap in the literature.

OBJECTIVES

The objective was to evaluate the efficacy and adverse events of psychological therapies for the prevention of migraine in adults.

METHODS

Criteria for considering studies for this review

Types of studies

We included the following studies in the review.

- Randomised controlled trials (RCTs) and cluster-RCTs
- Studies with at least 15 participants in any treatment or control arm at the post-treatment assessment
- Studies published (including electronically pre-published) in peer-reviewed scientific journals

Types of participants

Inclusion criteria

Adults (18 years or older) who reported episodic or chronic migraine with or without aura; if a study included other headache participants, we used data for migraine only if the study authors reported the data separately. We excluded studies if data were unavailable separately for participants with migraine. For the purposes of this meta-analysis, we did not require ICHD-verified diagnoses, although we intended to extract these data in order to examine diagnostic confirmation as a potential mediator of response.

Exclusion criteria

We excluded trials where the following occurred:

- migraine was secondary to an acute or progressive neurological condition (e.g. giant cell arteritis, raised intracranial pressure, multiple sclerosis, infection);
- the primary pain complaint of the participant was not migraine;
- participants had a headache condition other than migraine (e.g. tension-type headache, cluster headache, medication overuse headache).

Types of interventions

We included RCTs designed to test the efficacy of psychological treatment as an active treatment of primary interest if at least one arm of the trial provided a psychological intervention and there was a comparison arm. We defined credible psychological treatment as a treatment with definable psychotherapeutic content that an appropriately qualified healthcare professional delivered or supervised. The comparison arm could include another active treatment (psychological or medical), an attention-placebo (e.g. supportive counselling) or other placebo group, routine care, or waiting-list control. Therefore, the intervention arm could consist of a pharmacological plus a psychological arm, providing there was one arm with pharmacological treatment alone and the effect of the psychological therapy could be isolated. We included all RCTs regardless of treatment dose, migraine intensity and frequency, mode of delivery (e.g. individual, group), or medium of treatment delivery (e.g. face-to-face, internet).

Types of outcome measures

We included outcomes as either dichotomous or continuous data. The following outcomes drew on the recommendations proposed by the IHS Clinical Trials Subcommittee (Tfelt-Hansen 2000), and the guidelines for behavioural treatments of recurrent headache (Penzien 2005).

Primary outcomes

- Migraine frequency (we defined migraine frequency as either the number of days with migraine or the number of migraine attacks in the four-week period after treatment, based on participant report using a headache diary).

Secondary outcomes

- Responder rate: proportion of participants with migraine frequency reduction of more than 50% in the four weeks after treatment compared to the four weeks before treatment
- Migraine intensity (average intensity of migraine headache based on a simple numerical rating scale measuring pain intensity from mild, moderate or severe)
- Migraine duration (number of hours of migraine per day from a headache diary)
- Migraine medication usage, defined as
  - the number of migraines that were treated with acute symptomatic treatment
  - the number of doses consumed
- Mood (self-reported scales measuring depressive symptoms, anxiety-related symptoms, or distress, such as the Hospital Anxiety and Depression Scale, Centre for Epidemiological Study Depression Scale);
- Quality of life (self-reported questionnaire measures that assessed the impact of migraine on quality of life)
- Migraine-related disability
- Adverse events (the proportion of participants that reported an adverse event that was recorded during the study)

We extracted data for the first assessment that occurred following the intervention. For follow-up, we included the longest available follow-up, as long as it was within 12 months of the intervention.

Search methods for identification of studies

Electronic searches

We searched the following databases from their inception to 10 July 2018.

- Cochrane Central Register of Controlled Trials (CENTRAL; 2018, Issue 7) via the Cochrane Register of Studies Online (CRSO)
- MEDLINE and MEDLINE in Process (OVID) 1946 to 10 July 2018
- Embase (OVID) 1974 to 10 July 2018
- PsycINFO (OVID) 1974 to 10 July 2018

- CINAHL (EBSCO) 1982 to 10 July 2018

We used Medical Subject Headings (MeSH) where applicable, and also text word searching. The search strategies used can be found in Appendix 1. We searched for published and unpublished trials in all languages.

Searching other resources

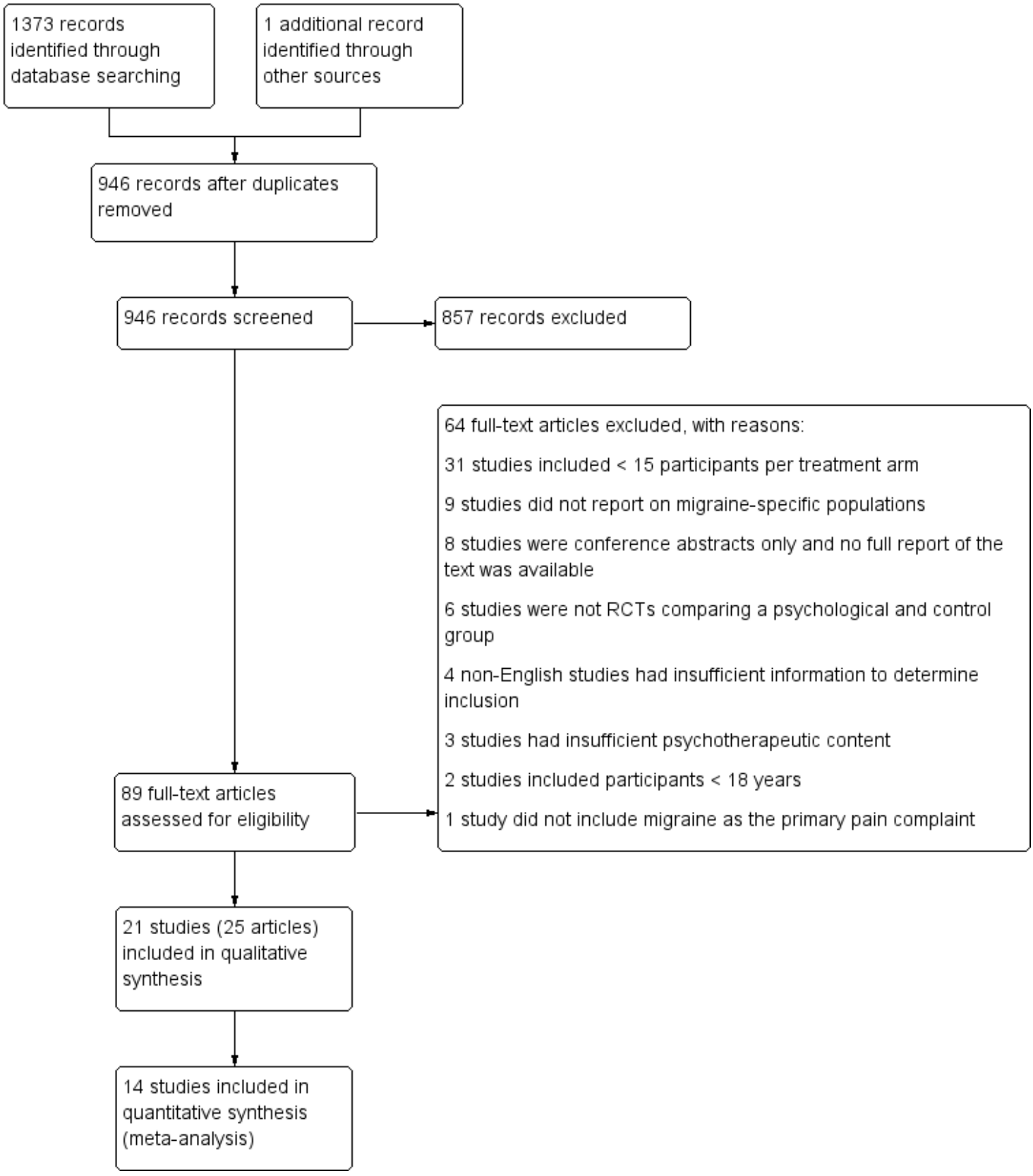
We handsearched the reference lists of included trials and performed citation searches of included trials and identified reviews in order to ensure that all available trials were represented. We searched the metaRegister of controlled trials (mRCT) (now replaced by the ISRCTN registry: http: // www.isrctn.com), clinicaltrials.gov (www.clinicaltrials.gov), and the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (apps.who.int/trialsearch/), for ongoing trials of psychological interventions and migraine. In addition, we checked reference lists of reviews, retrieved articles for additional studies, and performed citation searches on key articles. We contacted study authors, where necessary, for additional information.

Data collection and analysis

Selection of studies

Initially, we merged the results of the individual searches and removed all duplicates from the database search. Two review authors (LS, JD) independently shortlisted titles and abstracts of all identified articles. They removed clearly irrelevant articles based on inspection of titles and abstracts. Two review authors (LS, JD) independently assessed the full-text reports of relevant articles to determine whether or not the design of the study met the eligibility criteria. We contacted the study authors for clarification where there was ambiguity about whether a trial met the inclusion criteria. Finally, we linked multiple reports on the same study for the purposes of data extraction. Two review authors (LS, JD) listed the full-text articles that we had excluded in the Characteristics of excluded studies table, with the reason(s) for exclusion. We produced a PRISMA flow diagram to promote transparency of the search and systematic review process (Moher 2009; Figure 1).

Figure 1. Study flow diagram



Data extraction and management

We developed a data extraction form modified from those developed for similar Cochrane Reviews (e.g. Williams 2012). We extracted data on important characteristics of the study design, characteristics of participants, diagnosis (migraine with or without aura), time since diagnosis of migraine, type of intervention, treatment dosage, migraine intensity and frequency, mode of treatment delivery (e.g. individual treatment, face-to-face, group, internet), control intervention, qualifications of the therapist, and outcome measures. Two review authors (LS, JD) independently extracted data from each of the included studies, and entered these data into Characteristics of included studies tables in Review Manager 5 (RevMan 5) (Review Manager 2014).

Assessment of risk of bias in included studies

We assessed the risk of bias for each included study using the criteria developed in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2017). Two review authors (LS, JD) assessed the following risks for bias and resolved any discrepancies through consensus. The review authors entered data into the 'Risk of bias' tables and provided support for each judgement. We also constructed 'Risk of bias' figures (Figure 2; Figure 3).

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

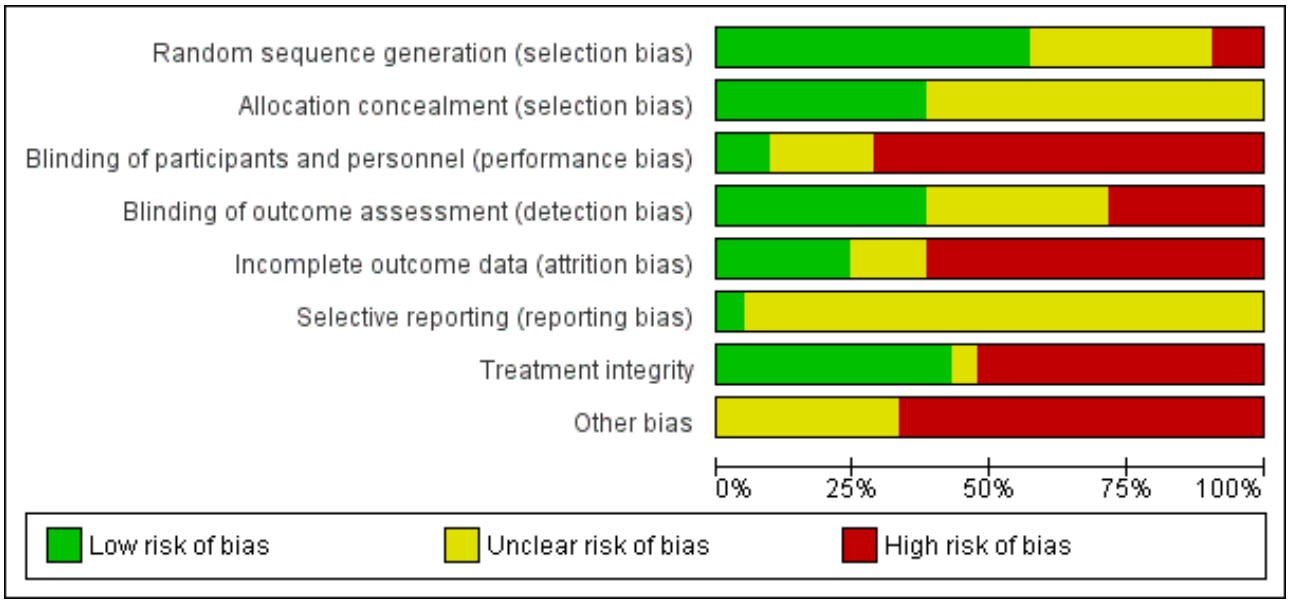


Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

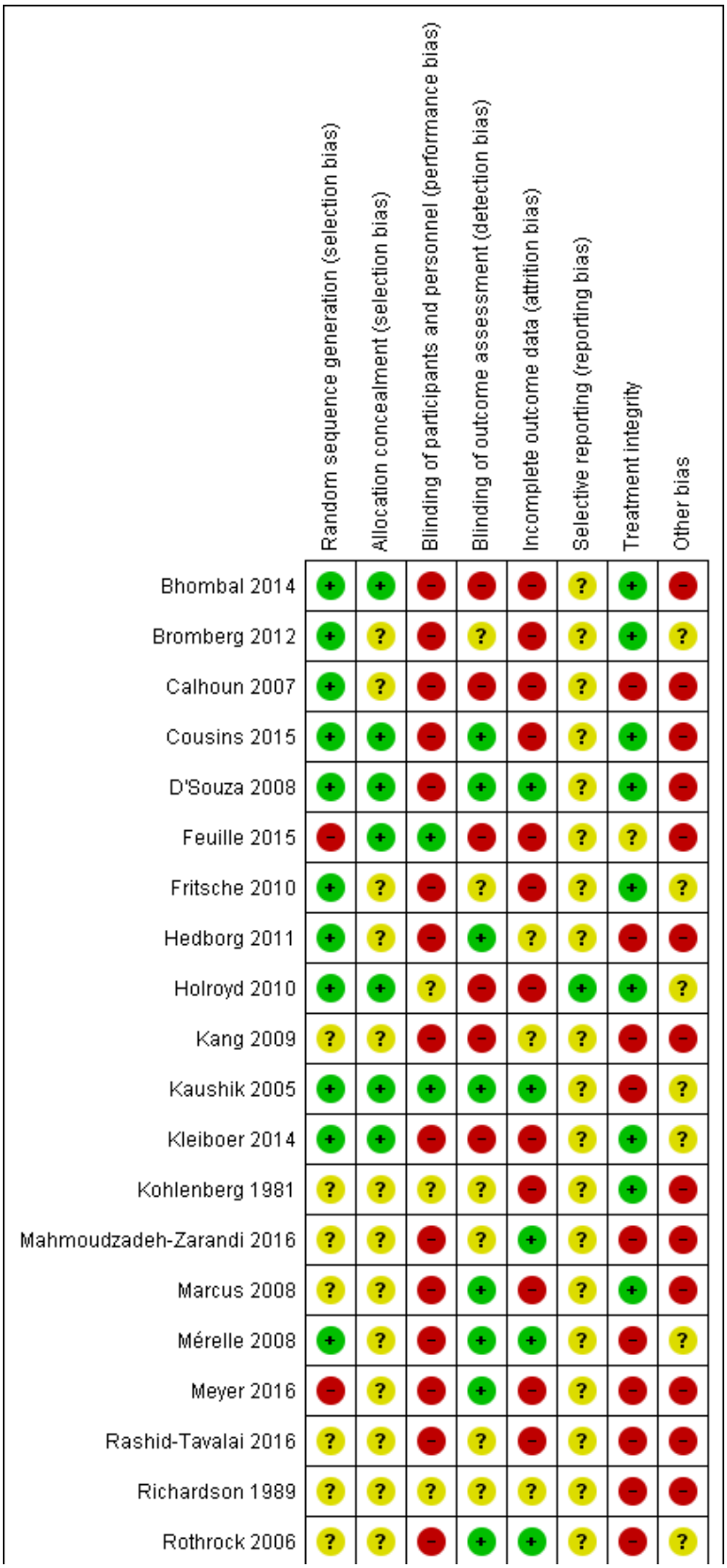
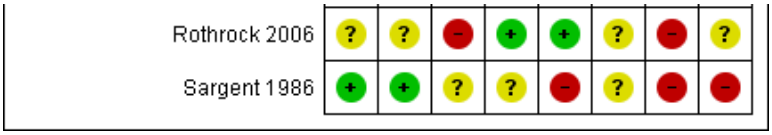


Figure 3. (Continued)



Random sequence generation (selection bias)

We determined the method the study authors utilised to generate a random sequence. We judged the study to be at a low risk of bias if the study authors used a random method to assign participants to interventions (e.g. computerised generation of number sequence; toss of a coin, random number table etc.). We considered the study to have an unclear risk of bias if the study authors did not state the manner in which they conducted randomisation and were unable to provide these data. We described the study as having a high risk of bias if the study did not conduct randomisation using a truly random procedure (e.g. counterbalanced, use of odd and even numbers, etc.).

Allocation concealment (selection bias)

We assessed the method the study authors used to conceal allocation prior to assignment. We rated those studies that adequately concealed allocation as having a low risk of bias. We deemed the study to have an unclear risk of bias if the allocation concealment was not described. We determined the study to have a high risk of bias when the allocation sequence was available to investigators prior to randomisation.

Blinding of outcome assessment (detection bias)

Since psychological treatments cannot blind personnel involved in treatment delivery, we based our assessment of risk of bias for blinding on whether assessments were conducted by researchers who were blind to the intervention to which participants had been allocated.

We deemed studies that blinded the assessors to the intervention to which the participant was allocated as at low risk of bias. We rated the study as having an unclear risk of bias if study authors did not state whether or not blinding was involved. We assigned a high risk of bias to studies where outcome assessors were not blinded.

Performance bias

As with detection bias, it is impossible to blind participants to interventions. Therefore, we deemed studies where treatment expectancy was measured and shown to be equivalent across interventions as being at low risk of bias. Where study authors did not include an assessment of treatment expectation, we rated studies as having a high risk of bias.

Attrition bias

We included a measure of the completeness of the follow-up data and how study authors dealt with cases of missing data because when participants are lost to follow-up, this introduces a source of potential bias to studies. We judged studies to have a low risk of bias where a high proportion of participants who started the treatment completed follow-up assessments (90% data or more available) or where most (more than 70%) data were available and an intention-to-treat analysis (ITT) was performed using a multiple imputation model. We judged the study as having high risk of bias where these criteria were not met and high rates of attrition were present or ITT analyses relied on less stringent methods (e.g. last-observation-carried-forward). If completion rates were not reported, we deemed studies to have an unclear risk of bias.

Selective reporting bias

We identified entries in clinical registries for all clinical studies to determine whether the study authors analysed all primary and secondary end points as they had originally planned. We deemed those studies that reported all end points using the analyses set out in the study register to be at low risk of bias. We judged the level of bias as unclear if a preregistered study was unavailable. We judged studies as having a high risk of bias if preregistered information demonstrated that the study authors reported different primary outcomes or did not report all measures in the final study report, or if study authors performed a selective analysis.

Treatment integrity

Treatment fidelity

We included an item to determine the integrity of the intervention administered. We judged studies that had a dedicated treatment manual and reported an assessment of the degree to which therapists adhered to that manual to be at low risk. If a treatment manual was not available, or therapist adherence was not measured, we deemed the risk to be unclear. If there was evidence that the intervention was not well adhered to, we judged the study to be at high risk of bias. We only considered studies to be at low risk of bias if the therapists were well trained and there was evidence of treatment fidelity (see below).

Training of the therapist

We assessed the training of the therapist. We deemed studies that reported on specific training of an appropriately qualified therapist for the study to be at low risk of bias. If the training of the therapist was not mentioned, we deemed the study to be at an unclear risk of bias. In order to be deemed at low risk of bias, therapists in the studies needed to have both sufficient training and fidelity checks.

Size of study

Cochrane Pain, Palliative and Supportive Care (PaPaS) recommends the following for assessing the risk associated with the size of a study and hence we used the conventions outlined below.

- Low risk of bias: more than 200 participants per treatment arm.
- High risk of bias: fewer than 50 participants per treatment arm.
- Unclear risk of bias: between 50 and 199 participants per treatment arm.

Measures of treatment effect

Where data were continuous, we measured the standardised mean difference (SMD) between the psychological treatment arm and the

comparator arm (with 95% confidence intervals (CIs)). Where data were dichotomous (e.g. proportion of responders), we determined the risk ratio (RR) and number needed to treat for an additional beneficial outcome (NNTB) for 50% or more in migraine frequency over four weeks, for the intervention versus control group.

We assessed the SMD at post-treatment and at follow-up. In the case of multiple time points, we defined post-treatment as the assessment that was closest to the end of the intervention and within three months. In the case of follow-up, assessment must have been made between three and 12 months after the end of the intervention. If more than one follow-up period met this criterion, then we used data from the longest available follow-up.

Unit of analysis issues

We halved the number of participants of the comparator arm where more than two active treatment arms met criteria for a credible psychological treatment and were compared to one comparator arm. This was in order not to overly weight the results of that study where both arms were included in the same analysis. While this method only partially overcomes the unit-of-analysis issue, an advantage was that analyses of heterogeneity across the two active treatment arms were possible and we noted that some comparator treatments were very different in content.

In future updates, if we identify any cluster trials, we will handle the data from these trials according to the methods described in the *Cochrane Handbook of Systematic Reviews of Interventions* (Higgins 2017).

Dealing with missing data

We contacted the study authors directly if data were missing from the original publication and requested that they provide sufficient data to allow us to calculate the effect size of interest. We gave study authors one month to respond, and we sent a reminder email at the end of a month to give them a further week to provide the data. This included studies that only reported a headache index. The rationale for this was that headache indices can differ between studies, typically including some information about intensity, frequency or duration of the migraine, or a combination of these. As such, it is not possible to know which of these measures have changed significantly. In these instances, we contacted the study authors by email to request that they provide the data on which they had calculated the headache index. We treated the study as having no useable data if responses from study authors were not received. We considered the potential impact on the results of the missing data in the Discussion section of the review.

Assessment of heterogeneity

We assessed and interpreted heterogeneity (I^2 statistic) in line with the guide outlined in the *Cochrane Handbook of Systematic Reviews of Interventions* (Deeks 2017).

- I^2 = 0% to 40%; not important
- I^2 = 30 to 60%; moderate heterogeneity
- I^2 = 50% to 90%; substantial heterogeneity
- I^2 = 75% to 100%; considerable heterogeneity

We considered the implications of heterogeneity in the Discussion section of the review.

Assessment of reporting biases

We assessed the likelihood that publication bias affected the results of the meta-analysis by inspection of known protocols that were registered and not published. We also used statistical methods to test for likely publication bias, including the examination of funnel plots and the use of the trim and fill method.

Data synthesis

We used RevMan 5 (Review Manager 2014), to analyse the data, and used a random-effects model.

Quality of the evidence

Two review authors (LS, JD) independently rated the quality of the evidence for the outcomes. We used the GRADE system to rank the quality of the evidence using the GRADEpro software (GRADEpro GDT 2015), and the guidelines provided in Chapter 11 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2017).

The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness, and publication bias) to assess the quality of the body of evidence for each outcome. The GRADE system uses the following criteria for assigning grade of evidence.

- High: we are very confident that the true effect lies close to that of the estimate of the effect.
- Moderate: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different.
- Low: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
- Very low: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

The GRADE system uses the following criteria for assigning a quality level to a body of evidence (Chapter 11, Schünemann 2017).

- High: randomised studies; or double-upgraded observational studies
- Moderate: downgraded randomised studies; or upgraded observational studies
- Low: double-downgraded randomised studies; or observational studies
- Very low: triple-downgraded randomised studies; or downgraded observational studies; or case series/case reports

Factors that may decrease the quality level of a body of evidence are:

- limitations in the design and implementation of available studies suggesting high likelihood of bias;
- indirectness of evidence (indirect population, intervention, control, outcomes);
- unexplained heterogeneity or inconsistency of results (including problems with subgroup analyses);
- imprecision of results (wide confidence intervals);
- high probability of publication bias.

Factors that may increase the quality level of a body of evidence are:

- large magnitude of effect;
- all plausible confounding would reduce a demonstrated effect or suggest a spurious effect when results show no effect;
- dose-response gradient.

We decreased the grade rating by one (−1) or two (−2) (up to a maximum of −3 to 'very low') if we identified:

- serious (−1) or very serious (−2) limitations to study quality;
- important inconsistency (−1);
- some (−1) or major (−2) uncertainty about directness;
- imprecise or sparse data (−1);
- high probability of reporting bias (−1).

In addition, there may be circumstances where the overall rating for a particular outcome needs to be adjusted as recommended by GRADE guidelines (Guyatt 2013a); for example, where one would have no confidence in the result, and would need to downgrade the quality of the evidence by three levels, to very low quality. In circumstances where there were no data reported for an outcome, we report the level of evidence as very low quality (Guyatt 2013b). The application of these GRADE criteria have changed since the protocol was published, due to updating of the GRADE criteria during that time.

Summary of findings

We included a 'Summary of findings' table to present the main findings in a transparent and simple tabular format, for psychological therapies compared with controls for adults with migraine at post-treatment. In particular, we included key information concerning the quality of evidence, the magnitude of effect of the interventions examined, and the sum of available data on migraine frequency during the four-week period after intervention, responder rate, migraine intensity, mood, migraine-related disability, and proportion of participants reporting adverse events during treatment. We included an additional table to describe the interventions that were used in all included studies.

Subgroup analysis and investigation of heterogeneity

We intended to examine the relative effectiveness of treatments for different levels of frequency of migraine at pretreatment assessment. In addition, we planned to investigate the relative efficacy of interventions for those with chronic versus episodic migraine, participants with migraine with and without aura, and whether participants in the study had ICHD-verified diagnoses of migraine, if sufficient data were available.

In terms of treatment characteristics, we intended to analyse separately those interventions with face-to-face treatment compared to those with only or predominantly phone or internet contact, and group versus individual mode of delivery. We also planned to examine separately the effectiveness of cognitive behaviour therapy (CBT) in the treatment of migraine. If sufficient studies met the inclusion criteria of this review, we planned on examining the relative efficacy of relaxation compared to biofeedback. Finally, if we identified a sufficient number of studies, we planned to analyse those that encouraged avoidance of migraine triggers with those that advocated exposure to triggers.

Sensitivity analysis

We planned no sensitivity analyses a priori, because we believed that the evidence base was likely to be too small for sensitivity analyses to be meaningful or reliable. However, we did conduct a post hoc sensitivity analysis for migraine-related disability to remove one outlier from the analysis to determine whether this affected the result.

RESULTS

Description of studies

Results of the search

We searched databases from their inception to July 2018 (see Figure 1). In total, we identified 1373 records through the database search, and an additional study through searching the trials registries. After duplicates were removed, there remained 946 unique abstracts. Two reviewers (LS, JD) independently reviewed these abstracts and retrieved 89 full-text articles, which they read in full. We excluded 64 of these articles for the reasons outlined in Excluded studies (below). Therefore, we included a total of 21 studies (from 25 articles) in the current review (Bhombal 2014; Bromberg 2012; Calhoun 2007; Cousins 2015; D'Souza 2008; Feuille 2015; Fritsche 2010; Hedborg 2011; Holroyd 2010; Kang 2009; Kaushik 2005; Kleiboer 2014; Kohlenberg 1981; Mahmoudzadeh-Zarandi 2016; Marcus 2008; Mérelle 2008; Meyer 2016; Rashid-Tavalai 2016; Richardson 1989; Rothrock 2006; Sargent 1986).

Included studies

We included 21 studies (see Characteristics of included studies). There were 2482 participants who entered the trials, and 2139 of those participants completed post-treatment assessment. Overall, this corresponded to an 86% completion rate across studies.

Studies varied in whether they reported demographic characteristics for completers or for all who enrolled in the study. Of those studies that reported age and sex, the mean age was 36.8 years and 1895 out of 2258 participants (84%) were female.

Fourteen studies recruited participants through advertisements or a combination of referral and advertisement, while the remaining seven studies recruited participants exclusively through a hospital, or specialist headache or neurology service.

Fourteen studies diagnosed migraine according to the International Classification of Headache Disorders (ICHD) criteria (Bromberg 2012; D'Souza 2008; Fritsche 2010; Hedborg 2011; Holroyd 2010; Kang 2009; Kaushik 2005; Kleiboer 2014; Mahmoudzadeh-Zarandi 2016; Marcus 2008; Mérelle 2008; Meyer 2016; Rashid-Tavalai 2016; Rothrock 2006).

Eleven studies reported including participants with migraine with and without aura (Bromberg 2012; Cousins 2015; Fritsche 2010; Hedborg 2011; Holroyd 2010; Kang 2009; Kaushik 2005; Kleiboer 2014; Mahmoudzadeh-Zarandi 2016; Mérelle 2008; Meyer 2016). The remaining studies did not report any diagnostic information.

Sixteen studies did not indicate how long participants had to be experiencing migraines in order to be eligible to take part in the trial. For the remaining studies, time since diagnosis inclusion criteria varied; in two studies, participants had to have been diagnosed with chronic or episodic migraine for at least three

months (Rashid-Tavalai 2016; Richardson 1989); in one study, time since diagnosis was at least six months (Cousins 2015); in two studies, time since diagnosis was at least 12 months (Bromberg 2012; Meyer 2016), and in one study time since diagnosis had to be more than two years (Sargent 1986).

The inclusion criteria related to migraine frequency over a four-week period differed considerably. Participants had to have at least two migraines per month in three studies (Bromberg 2012; Hedborg 2011; Richardson 1989), and one study reported baseline means as high as 24.2 migraines over a four-week period (Calhoun 2007). Not all studies reported migraine frequency at baseline, but the median of those that did (n = 12) was approximately 7.3 migraines per month.

Of the 21 studies, 15 had two arms (one active intervention group and one control group; Bhombal 2014; Bromberg 2012; Calhoun 2007; Cousins 2015; Fritsche 2010; Kang 2009; Kaushik 2005; Kleiboer 2014; Kohlenberg 1981; Mahmoudzadeh-Zarandi 2016; Marcus 2008; Mérelle 2008; Meyer 2016; Rashid-Tavalai 2016; Rothrock 2006); four had three arms (two active treatments and one control group; D'Souza 2008; Feuille 2015; Hedborg 2011; Richardson 1989); and two studies had four arms, in one of which three were active treatment and the fourth was the control group (Sargent 1986), and in the other there was a factorial design where participants either received psychological intervention or not, or pharmacotherapy or placebo (Holroyd 2010). The type of treatment, duration of treatment, and setting varied (Table 1).

The majority of active intervention arms were a form of behavioural or CBT. Seven studies included a behavioural intervention (either alone or combined with pharmacotherapy) as the treatment arm (Bhombal 2014; Calhoun 2007; Hedborg 2011; Holroyd 2010; Kleiboer 2014; Mahmoudzadeh-Zarandi 2016; Mérelle 2008). Five studies were classified as having a CBT intervention (Bromberg 2012 ; Cousins 2015; Fritsche 2010; Rashid-Tavalai 2016; Richardson 1989), and two had biofeedback (Kang 2009; Sargent 1986). Two studies used biofeedback as an adjunct treatment to either CBT (Kohlenberg 1981) or relaxation (Kaushik 2005). One study included two separate active treatment arms of relaxation and written emotional discourse (D'Souza 2008). The remaining interventions were used by one study only: eye movement desensitisation and reprocessing (Marcus 2008), relaxation (Meyer 2016), psycho-education (Rothrock 2006), and mindfulness (Feuille 2015).

The majority of studies (n = 12) employed an inactive control group (e.g. waiting list or standard care; Bromberg 2012; Cousins 2015; Hedborg 2011; Kang 2009; Kleiboer 2014; Mahmoudzadeh-Zarandi 2016; Marcus 2008; Mérelle 2008; Meyer 2016; Richardson 1989; Rothrock 2006; Sargent 1986). Three other studies used an active medication (Bhombal 2014; Kaushik 2005; Rashid-Tavalai 2016), three studies used an attention placebo to control for time and attention (Calhoun 2007; D'Souza 2008) or a pill placebo (Holroyd 2010), while the remaining three studies used an active control, to account for time and attention Feuille 2015; (Fritsche 2010; Kohlenberg 1981).

In 11 studies, all psychological content was administered face-to-face in clinic. In five studies, the intervention was only delivered at home, either via the internet (Bromberg 2012; Hedborg 2011; Kleiboer 2014), using bibliotherapy (Kohlenberg 1981), or through a home-based, group-delivered intervention (Mérelle 2008. These five studies conducted what are often referred to as 'minimal' interventions. That is, interventions that require a minimal amount of interaction with a therapist. The remaining five studies used a combination of face-to-face and home delivery of treatment.

Therapy sessions varied in terms of both the number and duration. The minimum dose was a single 20-minute session (Calhoun 2007), and the maximum was seven sessions of two hours' duration (Mérelle 2008; Rashid-Tavalai 2016). The variation in number and duration of sessions made it difficult to estimate the median, but approximately half the intervention arms consisted of four sessions or fewer.

We extracted meta-analytic data from 14 studies. We were unable to extract quantitative data from seven studies, as the necessary data for primary and secondary outcomes were not reported and study authors did not provide it upon request (Bhombal 2014; Calhoun 2007; Feuille 2015; Kohlenberg 1981; Marcus 2008; Meyer 2016; Sargent 1986).

Excluded studies

We excluded 64 studies from the current review (see Characteristics of excluded studies).

We excluded 31 studies due to an insufficient sample size, with fewer than 15 participants completing one of the study arms (Andersson 2003; Andreychuk 1975; Attfield 1979; Bild 1980; Blanchard 1978; Blanchard 1990b; Blanchard 1991; Brown 1984; Daly 1983; Devineni 2005; Dindo 2014; Doerr-Proske 1985; Gerhards 1985; Grazzi 2002; Haag 1987; Hart 1984; Holroyd 1989; Holroyd 1995; Jurish 1983; Lambley 1978; Main 2002; Mitchell 1971; Mullinix 1978; Philips 1977; Reading 1984; Smitherman 2016; Stout 1985; Trinka 2002; Warner 1975; Williamson 1984; Wylie 1997).

Nine studies included participants with migraine in a group of participants with other forms of headache-related pain, including tension-type headache or medication overuse headache, and we could not extract the migraine data (Bakhshani 2016; Basler 1996; Blanchard 1990a; Blanchard 1997; Holroyd 1988; Martin 1989; Martin 2014; Mullally 2009; Wachholtz 2008).

We excluded eight studies that were abstracts of conference presentations or a dissertation, and where we could identify no full report of the trial (Grazzi 2016; Martin 2017; Mizener 2004; Mullally 2001; Sharma 2010; Sorbi 2011; Varkey 2010; Wober 2009).

We excluded six studies because they were not RCTs (e.g. allocation to treatment was not randomised; no control group; a meta-analysis or commentary; Blanchard 1985; Cooper 2016; Gerber 1985; Grazzi 2017; Martin 2015; Voerman 2014).

We excluded four non-English studies as we were unable to find the publication, there was insufficient information to determine whether or not they were suitable from the abstract, and study authors did not respond to requests for information (Grigorieva 2003; Guang'an 2001; Nasiri 2016; Safarinia 2015).

We excluded three studies that had insufficient psychotherapeutic content (Dittrich 2008; Hoffmann 2008; Lemstra 2002), and two studies that included participants who were ineligible (children aged under 18) (Anderson 1975; Wang 2005).

We excluded Wojciechowski 1984 because migraine was not the primary pain problem.

Risk of bias in included studies

Two reviewers (LS and JD) rated all of the 21 included studies for indicators of risk of bias in nine categories. The categories were: random sequence generation and allocation concealment (selection bias); blinding of participants and personnel (performance bias); blinding of outcome assessors (detection bias); incomplete outcome data (attrition bias); selective reporting (reporting bias); treatment integrity (treatment fidelity and training of therapists); and sample size. The results are discussed below and the ratings for each of these criteria are reported in Figure 2 and Figure 3.

No study had low risk of bias for all nine categories, and only one had low risk of bias for random sequence generation, allocation concealment, and blinding of participants and personnel (Kaushik 2005). The majority of studies had high risk of bias in two to five categories; one had high risk of bias for one category only (Kaushik 2005).

Allocation

Random sequence generation

Of the 21 studies, we judged 12 studies as being at a low risk of bias in relation to randomisation because they used appropriate randomisation procedures (e.g. computerised generation of number sequence; toss of a coin, random number table etc.). Two of the studies described randomisation practices that did not reflect a truly random procedure and so we rated them as being at high risk of bias. The remaining studies did not describe their studies in sufficient detail to allow us to assess risk of bias, and hence we rated them as having an unclear risk of bias.

Allocation concealment

Only eight studies described explicitly concealing allocation and we judged them to be at low risk of bias. No studies indicated explicitly that they had concealed allocation, and therefore, for the remaining 13 studies, we judged the risk of bias to be unclear.

Blinding

Performance bias

Fifteen studies did not include an assessment of treatment expectation and we judged them to be at high risk of bias. In four studies, expectations in the control arm were not matched and therefore we concluded that the risk of bias was unclear. There were only two studies that deliberately matched expectations in a control arm and the intervention arm, both of which we judged to be at a low risk of performance bias.

Detection bias

We found eight studies that had personnel assessing outcomes who were blinded to group allocation and therefore we allocated these studies as having low risk of detection bias. We judged seven studies as having unclear risk of bias, and six studies as having high risk of detection bias as it was clear that those providing the assessment were not blind to treatment allocation.

Incomplete outcome data

We identified six studies as having low risk of attrition bias because they had a sufficiently low attrition rate (< 10%) or used ITT analysis with a relatively low attrition rate (< 30%), or both. We judged two studies as having unclear attrition bias due to a failure to report attrition rate. For the remaining studies, the attrition rate was either greater than 10% with no ITT analysis, or greater than 30%, and we judged those 13 studies to be at high risk of bias.

Selective reporting

We were able to identify a registered trial that reported primary and secondary outcomes for one study and therefore we judged this study to be at low risk of bias. We could not identify the remaining 20 studies in a trials registry, and therefore we judged the risk of reporting bias to be unclear.

Other potential sources of bias

Treatment integrity

In order for treatment integrity to be considered at a low risk of bias, both treatment fidelity and therapist training needed to be at low risk of bias. This is because we deemed that for the treatment to have integrity, it needed to be consistent, adhered to and delivered by people with appropriate training. In nine of the included studies, we rated the risk of bias as low based on the treatment fidelity and training of the therapists both being at low risk for bias. For 11 studies, there was no mention of a standardised manual, therapist training, or check of treatment fidelity. Therefore, we judged these studies to be at high risk of bias for both domains of treatment integrity. In one study, a manualised intervention was used although the qualifications of therapists and the training were not described and therefore we judged the risk of bias to be high.

Size of study

For sample size, we judged seven studies as having unclear risk of bias as they had between 50 and 199 participants per arm. We allocated a judgement of high risk of bias to 14 studies that had fewer than 50 participants per arm. We judged no studies as having low risk of bias.

Effects of interventions

See: **Summary of findings for the main comparison** Psychological therapies compared with controls for managing migraine in adults: post-treatment outcomes

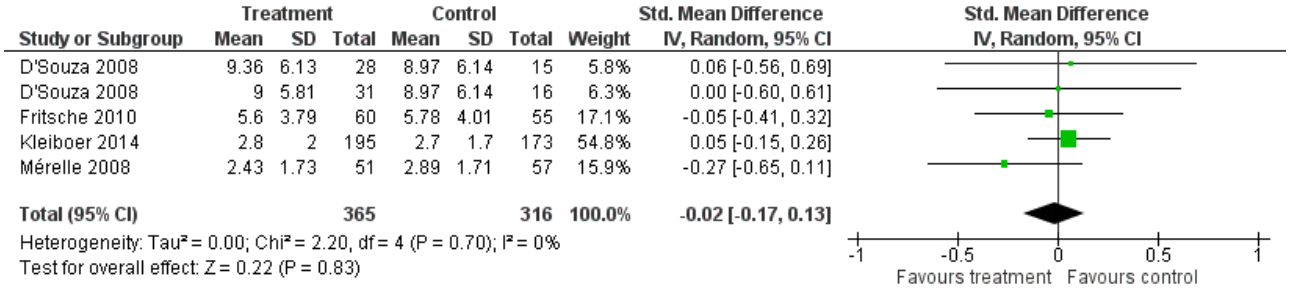
Post-treatment

Primary outcome: migraine frequency (number of days or number of migraine attacks over a four-week period following intervention)

Of the 21 included studies, four studies (681 participants) reported data for the continuous primary outcome of migraine frequency for four weeks following treatment. One study used a 30-day diary (rather than four weeks), but for the purposes of this review we included these data (Kleiboer 2014). The analyses demonstrated that there was no evidence of an effect for migraine frequency in groups that received psychological interventions in comparison to the control groups (SMD −0.02, 95% CI −0.17 to 0.13; P = 0.83; Analysis 1.1). Therefore, we found no evidence of an effect of psychological interventions on migraine frequency (Figure 4). The GRADE quality rating for this outcome was very low, meaning we have very little confidence in the effect estimate and the true effect is likely to be substantially different from the estimate of effect. We downgraded this outcome three times to very low quality

due to very serious limitations to study quality and sparse data (imprecision). See Summary of findings for the main comparison.

Figure 4. Forest plot of comparison 1. Treatment versus control (post-treatment), outcome 1.1: reduction in migraine frequency



Secondary outcomes

We downgraded all secondary outcomes three times to very low quality due to very serious limitations to study quality and sparse data (imprecision). Some outcomes, notably migraine-related disability and adverse events, were also affected by inconsistency. Therefore, we have very little confidence in the effect estimate and the true effect is likely to be substantially different from the estimate of effect reported below.

Responder rate

Four studies (338 participants) assessed the proportion of people who reduced the frequency of their migraine in the four weeks following intervention compared to the four weeks prior to the intervention. Fifty-four percent (101/186) of participants who received psychological therapy had a 50% or greater reduction in migraine frequency compared with 24% (37/152) of those who received a control intervention (RR 2.21, 95% CI 1.63 to 2.98; P < 0.001; Analysis 1.2). This equates to only three participants needing to have the intervention for one to experience a 50% reduction in migraine frequency (NNTB 3) and indicates that twice as many participants who received psychological treatment were classed as responders than in the control group.

Migraine intensity

Four studies (685 participants) reported this outcome. There was no evidence of an effect for migraine intensity in groups that received psychological interventions in comparison to the control groups (SMD −0.13, 95% CI −0.28 to 0.02; P = 0.09; Analysis 1.3).

Migraine duration

No studies assessed migraine duration (number of hours of migraine per day).

Migraine medication usage

For migraine medication usage, we found two available studies reporting outcomes on 483 participants, and there was no evidence of an effect of psychological interventions in comparison to the control group (SMD −0.06, 95% CI −0.35 to 0.24; P = 0.72; Analysis 1.4).

Mood

Four studies (432 participants) reported this outcome. There was no evidence of an effect of psychological interventions compared to control for mood (MD 0.08, 95% CI −0.33 to 0.49; P = 0.70; Analysis 1.5).

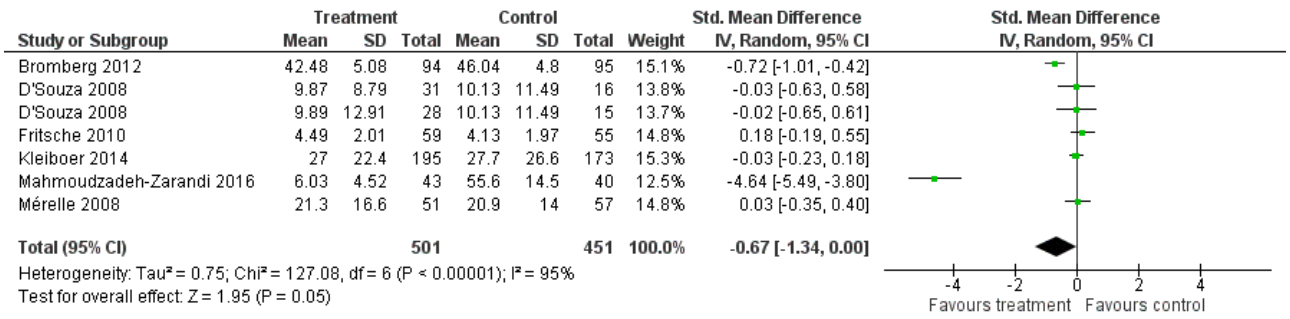
Quality of life

Four studies (565 participants) reported this outcome. There was no evidence of an effect of psychological interventions compared to control for quality of life (SMD −0.02, 95% CI −0.30 to 0.26, P = 0.89; Analysis 1.6).

Migraine-related disability

Six studies (952 participants) reported this outcome. There was no evidence that psychological interventions post-treatment had an effect for migraine-related disability (SMD −0.67, 95% CI −1.34 to 0.00; P = 0.05; Analysis 1.7; Figure 5).

Figure 5. Forest plot of comparison 1. Treatment versus control (post-treatment), outcome 1.7: migraine-related disability



One study was an outlier with a very large mean difference between the treatment and control group (Mahmoudzadeh-Zarandi 2016; Figure 5). Omitting this outlier in a sensitivity analysis made no difference to the conclusion of no evidence of an effect of psychological treatment on migraine-related disability (SMD −0.12, 95% CI −0.41 to 0.18; P = 0.45; 5 studies, 869 participants), although it did reduce the numerical size of the SMD.

Adverse events

Two studies (208 participants) reported this outcome. There were nine adverse events in 107 (8%) participants in the intervention group, and 30 adverse events in 101 (30%) participants in the control group (RR 0.16, 95% CI 0.00 to 7.85, P = 0.36; Analysis 1.8). Only two studies reported adverse events and so we were unable to draw any conclusions.

Follow-up outcomes

Only four studies reported any follow-up data. Follow-ups ranged from four months following intervention to 11 months following intervention. We downgraded all follow-up outcomes three times to very low quality due to very serious limitations to study quality (problems with blinding, potential selective reporting, and incomplete outcome data) and sparse data (imprecision). Therefore, we have very little confidence in the effect estimate and the true effect is likely to be substantially different from the estimate of effect reported below.

Primary outcome: migraine frequency

Two studies (421 participants) reported outcomes for migraine frequency at follow-up. One between three and four months' following intervention (Cousins 2015), and the other between five and six months after intervention (Kleiboer 2014). There was no evidence of an effect for those participants in the intervention group compared to those in the control group (SMD − 0.11, 95% CI −0.31 to 0.08; P = 0.24; Analysis 2.1).

Secondary outcomes

Responder rate

Only a single study (368 participants) provided data for responder rate at follow-up (Kleiboer 2014). In this study 76 of the 195 participants who received psychological therapies reported that they had a reduction of 50% or more in migraine frequency six months after treatment (39%), compared with 57 out of 173 in the control condition group (33%) (RR 1.18, 95% CI 0.90 to 1.56; P = 0.23). Therefore, there was no evidence of an effect for those participants in the intervention group compared to those in the control group.

Migraine intensity

No studies reported data for migraine intensity.

Migraine duration

No studies assessed migraine duration.

Migraine medication usage

For migraine medication usage, we found two available studies reporting follow-up outcomes on 421 participants, and there was no evidence of an effect of psychological intervention in comparison to the control group (SMD 0.02, 95% CI −0.17 to 0.21; P = 0.83; Analysis 2.2).

Mood

At follow-up based on three studies of 247 participants, there was no evidence of an effect of psychological interventions compared to control for mood (SMD −0.08, 95% CI −0.35 to 0.18; P = 0.54; Analysis 2.3).

Quality of life

Two studies (424 participants) reported this outcome. There was also no evidence of an effect of psychological intervention compared to control for quality of life (SMD 0.13, 95% CI −0.07 to 0.32; P = 0.20; Analysis 2.4).

Migraine-related disability

Three studies (544 participants) reported this outcome. Similarly, there was no evidence that psychological interventions had an effect for migraine-related disability compared to control conditions (SMD −0.04, 95% CI −0.21 to 0.13; P = 0.65; Analysis 2.5).

Heterogeneity

We conducted heterogeneity analyses for each of the analyses reported above. Post-treatment, we found considerable heterogeneity for the following outcomes: migraine-related disability (6 studies, 952 participants; I^2 = 95%; P < 0.00001; Analysis 1.7) and adverse events (2 studies, 208 participants; I^2 = 86%; P = 0.007; Analysis 1.8). At follow-up, we did not find significant heterogeneity in outcomes.

Subgroup analyses

We were unable to conduct the planned subgroup analyses, given the small number of studies in each primary and secondary outcome analysis.

DISCUSSION

Summary of main results

The main aims of this review were to determine whether psychological therapies for migraine had any effect on migraine frequency and other migraine-related outcomes in comparison to control. We identified 21 studies with 2482 participants. Of those studies that reported age, sex, and migraine frequency, most participants were female (84%), averaged 37 years old, and experienced migraine for a median of seven days per month. The majority of psychological treatments included in the review were cognitive-behavioural or behavioural in orientation. The primary outcome of the review was migraine frequency in the four weeks following intervention and the secondary outcomes were responder rate, migraine intensity, migraine duration (number of hours of migraine per day), migraine medication usage, mood, quality of life, migraine-related disability, and adverse events (proportion of participants that reported an adverse event during the study or during the follow-up period). We conducted analyses immediately post-treatment and at follow-up.

Post-treatment

For the primary outcome of this review, migraine frequency (days or attacks of migraines in the four weeks following intervention),

we did not find evidence of an effect of psychological interventions for migraines compared to control at post-treatment. This was based on a small number of very low-quality studies that were not representative of all the included studies (see below for a discussion). The GRADE quality rating for this outcome was very low, meaning we have very little confidence in the effect estimate and the true effect is likely to be substantially different from the estimate of effect. We downgraded this outcome due to very serious limitations to study quality and sparse data (imprecision).

More participants in the intervention arm reported a 50% reduction in migraine frequency in the four weeks following intervention compared to the four weeks prior to intervention than those in the control arm. The results indicated that the likelihood of at least 50% reduction in migraine frequency was twice as great from psychological treatment than from control (i.e. 54% of those in the intervention group could be classed as responders, while only 24% of the control improved by 50% or more; RR 2.21) and only three people needed to receive psychological treatment for one to benefit by at least a 50% reduction in migraine (NNTB 3). However, the quality of evidence was also very low due to serious limitations to study quality and imprecision. Therefore, we are not confident in the size of the estimated effect and future research would be likely to change the result.

It is notable that although the analyses for migraine frequency and responders both included data from four studies, there was only one study that overlapped between the analyses (Mérelle 2008). For those studies with migraine frequency as the outcome, three were either minimal therapeutic contact or internet-based trials (D'Souza 2008; Fritsche 2010; Kleiboer 2014). In contrast, three out of four psychological interventions in the responder analysis were face-to-face interventions (Holroyd 2010; Kang 2009; Mérelle 2008), and three investigated the efficacy of multimodal behavioural interventions (Hedborg 2011; Holroyd 2010; Mérelle 2008), with the remaining trial testing a biofeedback-based intervention (Kang 2009). It may be that different length of treatment or absence of face-to-face interaction, or both, may account for the differences in outcome. Future research directly comparing face-to-face and minimal intervention would be needed to confirm whether this was the source of differences in outcomes across analyses.

Of the seven other secondary outcomes that we assessed, there was no evidence of an effect on other migraine-related outcomes. That is, there was no evidence of an effect of psychological interventions on the outcomes of migraine intensity, migraine medication usage, mood, quality of life or migraine-related disability. Only two studies reported adverse events and so there was insufficient evidence to draw a conclusion. Despite the fact that number of migraine days prospectively monitored over a four-week period is one of the outcomes that has been endorsed as a primary outcome for clinical trials in migraine by the IHS (Tassorelli 2018), only two studies of psychological interventions had data on this variable. There were also no data available for migraine duration.

Follow-up

Very few trials reported outcomes at any follow-up. There was no evidence of an effect of psychological interventions compared to the control condition on any outcome. Unfortunately, overall, we judged the quality of the evidence to be very low, due to very serious study limitations (problems with blinding, potential selective reporting, and incomplete outcome data), and imprecision. Therefore, we believe that it is likely that the estimates found in this meta-analysis would change if new evidence emerged.

Overall completeness and applicability of evidence

We were able to extract some data from 14 of the 21 identified studies, but no outcome had more than six comparisons for the meta-analysis. This strongly suggests that there are no standardised outcome measures for evaluating psychological interventions in the management of migraine. We identified a priori that the migraine frequency (number of days with a migraine over four weeks) was the primary outcome, but we were only able to extract these data from two of the 21 studies. We therefore also included studies that reported the number of migraine attacks over a four-week period (see Differences between protocol and review below). Future research should consult the IHS guidelines in choosing primary and secondary outcomes for trials of psychological interventions for people with migraine (Tassorelli 2018). Our reason for nominating migraine frequency as the primary outcome was that other Cochrane Reviews of treatments for the prevention of migraine have done so (e.g. Linde 2013a; Linde 2013b), as have other non-Cochrane reviews (e.g. Schiapparelli 2010). If the aim is for psychological therapies to be an alternative to pharmacological treatments in the management of migraine, then it is important that they are judged by the same criteria. This is particularly the case where psychological therapies are used as an adjunct to pharmacotherapy. We were unable to draw conclusions about whether psychological interventions were associated with a higher proportion of people experiencing adverse events, since adverse events were rarely reported (2 studies) and future research should ensure that adverse outcomes are assessed and reported.

The seven studies from which we were unable to extract data included the only studies of mindfulness-based meditation and eye movement desensitisation and reprocessing (Bhombal 2014; Calhoun 2007; Feuille 2015; Kohlenberg 1981; Marcus 2008; Meyer 2016; Sargent 1986). This means that the effects of these two interventions were not represented in this review. It has also been suggested that cognitive behavioural approaches that focus on exposing people with migraine to triggers, as opposed to avoiding triggers, may produce better outcomes (e.g. Martin 2009). However, we could not include any studies of CBT that exposed participants because the only available study presented outcomes for a combined group of people with migraine and tension-type headache. We are aware of one study whose final results should be known after publication of our review (Martin 2017). Further, we were unable to comment on the likely long-term maintenance of psychological interventions for the management of migraine because few studies followed up participants over the longer term.

Quality of the evidence

We have provided a single 'Summary of findings' table (Summary of findings for the main comparison) for short-term (post-treatment) outcomes of psychological interventions in the management of migraine. We did not summarise long-term (follow-up) findings in a table due to insufficient studies reporting follow-up outcomes. We will consider adding this in future updates if there are enough data. We judged all outcomes to be of very low quality, which means we have very little confidence in the effect estimate and the true effect is likely to be substantially different from the estimate of effect. We downgraded all outcomes due to imprecision and very

serious limitations to the study design. However, we could have downgraded many of the outcomes for additional reasons. For example, we could have further downgraded both adverse events and migraine-related disability due to inconsistency, but we had already downgraded three times to very low. Nevertheless, this underscores our lack of confidence in the observed estimates of effect sizes.

There were no studies in this review that we rated as having a low risk of bias for all indicators. We could find only one study that referred to a published trial protocol being registered, and we were unable to identify registered protocols for the remaining trials. As such, the risk of bias for all but one study was unclear in relation to selective reporting criteria. This is particularly problematic in an area of research where the outcome measures differ markedly between studies, and the primary outcome measure is not standardised.

The risk of bias was either unclear or high in the majority of trials for random sequence generation, blinding of outcome assessors (detection bias) and attrition bias. In psychological trials, the blinding of participants is difficult, and only two of the trials included a credible 'placebo' type intervention (low risk of performance bias), and only one of those assessed expectancy to ensure that expectancy alone could not account for any treatment effect. Finally, the sample sizes of studies were typically small and therefore likely to be unreliable.

Potential biases in the review process

There are potential biases in this review as a result of the incomplete data reported in a number of studies. There is a long history of research into psychological interventions for migraine, with some of the included studies being published as early as the 1980s (Kohlenberg 1981; Richardson 1989; Sargent 1986). We tried to identify any of the study authors and their current academic affiliations in an attempt to get additional data, but we were unable to locate some and received few responses. Only one author from a single study provided additional data (Cousins 2015). Authors of RCTs should make their data publicly available in data repositories. This would help to render more studies eligible for meta-analysis.

In addition, in a number of studies, authors had recruited both adults with migraine and adults with tension-type headache, but reported the outcomes combined (Bakhshani 2016; Basler 1996; Blanchard 1990a; Blanchard 1997; Holroyd 1988; Martin 1989; Martin 2014; Mullally 2009; Wachholtz 2008). Again, we emailed these authors for aggregated data but only one responded with relevant data (Hoffmann 2008). There is an absence of evidence to know whether or not people with tension-type headache respond similarly to psychological interventions and therefore it is paramount that data are presented separately for the two groups. There is an argument that the causal and maintaining factors for tension-type headache and migraine differ, but whether people with migraine and tension-type headache differ in their response to psychological therapy is unknown. Research is needed to determine whether people with migraine and tension-type headache respond equally to psychological therapy as there is very little available evidence to support or refute this hypothesis.

Combining data from "days with migraine" and "number of migraines" may be viewed as a limitation but given that both are indicators of migraine frequency, we felt that combining them was the best available option. Regardless of the decision, the conclusion of the review would remain unchanged.

Finally, there were four abstracts for which we were unable to find the journal article. All of them were written in languages other than English, there was insufficient information to determine whether or not they were suitable from the abstract. Study authors did not respond to requests for information, and we judge that they are unlikely to ever respond. We were unable to include them in the review and this could add another source of bias.

Agreements and disagreements with other studies or reviews

There are previous reviews that have investigated particular types of intervention for people with migraine or related disorders. All of those have found that psychological interventions are effective in the management of migraine, which is at odds with the findings of this review. Most recently, there has been an opinion piece that provided an update on the evidence of efficacy for behavioural interventions (those psychological interventions that focus on changing behaviours) for migraine (Kropp 2017). This opinion piece concluded that behavioural interventions were equally as efficacious as pharmacological interventions in the prevention of migraine. Although the authors broadly reviewed the literature on behavioural interventions for migraine, there was no attempt to provide a full synthesis of outcomes, nor to meta-analyse the data.

Nestoriuc 2007 conducted a meta-analysis of biofeedback-based interventions for treating adults with migraine. The meta-analysis reported data from biofeedback training for participants with migraine. Their results suggested that biofeedback had a medium effect size (d = 0.58) in the treatment of migraine-related outcomes. Their meta-analysis differed from ours because in this Cochrane Review we included a range of psychological interventions (as opposed to biofeedback only), and had more stringent inclusion criteria. Nestoriuc 2007 included both controlled and uncontrolled trials, and their sample size exclusion criterion was fewer than four participants. As a result, their meta-analysis was based on trials with even smaller sample sizes, and pooled data from migraine intensity, frequency, and duration into the analysis. We excluded the majority of their included studies since our inclusion criteria specified that trials had to be RCTs and have at least 15 participants per arm.

The only other relevant reviews combined data for interventions for the treatment of tension-type headache and migraine. Gaul 2016 recently completed a narrative review of the literature on 'integrated multidisciplinary care' for the treatment of migraine in adults and concluded that multidisciplinary approaches are "reasonable and efficient" (p. 1181). However, as is common with narrative reviews, there was no systematic search nor study data selection process. A meta-analysis for the efficacy of self-management programmes for the treatment of migraine had similar results to those reported in our Cochrane Review (Probyn 2017). It found that there was no evidence of an effect of self-management on headache frequency. However, they did find a small effect on migraine-related disability and mood, favouring self-management approaches compared to controls. This was a well conducted, preregistered meta-analysis, but it included people with tension-type headache as well as people with migraine. It remains unclear, as previously discussed, whether these groups respond differently to psychological intervention.

Similarly, Sullivan and colleagues completed a systematic review of psychological interventions for adults with migraine (Sullivan 2016). They included 24 studies, seven of which included adults with migraine and tension-type headache (and the remainder adults with migraine). They examined the data qualitatively and concluded that 15 of 18 studies reported a beneficial effect of psychological intervention compared to control on measures of headache outcome. They also found positive effects of psychological therapy compared to control for psychological outcomes. However, in their methodology, they analysed outcomes across different time points together and indicators of headache severity, frequency, or a combination. Prior to the publication of the 'Guidelines for trials of behavioural treatments for recurrent headache' (Penzien 2005), most study authors used a headache index as the main outcome. We excluded these studies where frequency could not be separated from severity. Therefore, the pool of studies in our review was different from Sullivan 2016. Nonetheless, their results and our results differed due largely to the different inclusion criteria and pooling of results across multiple outcomes. However, both reviews agreed with the National Institute for Health and Care Excellence (NICE) recommendation that there was a need for more high-quality RCTs of psychological interventions to manage migraine (NICE 2015).

We agree with Sullivan 2016 that there needs to be more consistency in the reporting of outcomes in future research. A position paper by the IHS indicated that, in clinical trials for migraine, the primary outcome should be either migraine days, reduction in moderate to severe migraine days, or the proportion of people who had a 50% or greater reduction in migraine (Tassorelli 2018).

AUTHORS' CONCLUSIONS

Implications for practice

There is an absence of high-quality evidence to support or refute the efficacy of psychological treatments in the management of migraine. We did find that compared to mostly inactive controls, participants who received a psychological intervention were more likely to have a 50% or greater reduction in migraine frequency. Our results showed that twice as many participants who received a psychological therapy reported a 50% reduction in migraine frequency compared to control, such that participants receiving psychological interventions were more likely to report a reduction in frequency following intervention (540/1000 in the psychological therapy group compared to 240/1000 in the control group; RR 2.21). It is important to note that these results are based on poor-quality data, and therefore we cannot be confident in the effects reported here. They are also at odds with the results on our primary outcome of migraine frequency. Nevertheless, it has been noted above, that three out of four trials in the migraine frequency analysis were minimal interventions (i.e. self-directed, home-based or internet-delivered interventions) with minimal input from the therapists involved. In contrast, the majority of studies in the responder analysis were face to face, and related to multimodal behavioural interventions. Therefore the differing results could relate to the type of psychological therapy. Unfortunately, there were too few studies to test this possibility. It is also possible that while psychological interventions do not reduce migraine frequency across all participants, but a subgroup of participants respond well. From the analyses presented here approximately only three participants needed to be treated for one to benefit, which is comparable to commonly prescribed medications (e.g. topiramate (Linde 2013)), and compares favourably to others (e.g. gabapentin or pregabalin (Linde 2013b); other antiepileptics (Linde 2013a)). We urge caution, however, because the quality of the evidence was very low according to GRADE, and as a result, we have little confidence in the estimate of effect. From the two available studies, we were unable to draw conclusions as there was insufficient evidence.

For adults with migraine

We found an absence of high-quality evidence for whether psychological interventions have a role in the management of migraine and therefore we are uncertain whether there is any difference between psychological therapies and controls. People who received a psychological intervention did not overall have a different migraine frequency from those who received a control condition (like a waiting list) although more people who received a psychological intervention responded to treatment than in the control group (i.e. had a 50% or greater reduction in migraine frequency). According to our analysis of number needed to treat for an additional beneficial outcome, one in three participants responded. Therefore, psychological therapy could be an alternative for some people. However, the evidence base was very low quality and we are not very confident in these estimates.

For clinicians

Given the lack of an effect of psychological therapies on migraine frequency, and the lack of an effect of intervention on long-term outcomes, clinicians should proceed cautiously.

For policy makers

Given the absence of high-quality evidence to support the efficacy of psychological treatments in the management of migraine, policy implications revolve largely around the need for high-quality evidence on which to base future policy decisions.

For funders of the intervention

The absence of high-quality evidence for psychological interventions for managing migraine means that this review has few implications for funders of the intervention in routine care. However, this review strongly suggests that there is a need to fund high-quality randomised controlled trials (RCTs) of psychological interventions with appropriate follow-up to improve the evidence base for psychological therapies for managing migraine.

Implications for research

General implications

There is a strong need for high-quality RCTs of psychological interventions for the management of migraine. Despite a long history of psychological intervention for migraine, the evidence is very low quality and, as a result, estimates of the effect of psychological treatments are uncertain, due to the high risk of bias identified in the majority of trials and due to very serious study limitations and imprecision. The International Headache Society (IHS) position statement on the design of clinical trials for chronic migraine guides researchers to ensure that future research overcomes the problems we identified in this review (Tassorelli 2018). The specific implications for research design, measurement, and transparency of research data are listed below.

Design

One difficulty in conducting this review was the number of studies in which authors only reported group aggregate data for participants with migraine and tension-type headache, where the data were combined within the study. There are no available data to assess whether adults with migraine and tension-type headache respond similarly or differently. Therefore it is important that when interventions are developed for the management of adults with migraine and tension-type headache, data should be reported for each of the headache types separately. Tassorelli 2018 outlines the way in which individuals with types of headache other than migraine (e.g. tension-type headache, medication overuse headache) should be treated in clinical trials. For example, they recommend that adults with migraine can be included if they also have tension-type headache, as long as the person is able to distinguish the two types of headache clearly. Similarly they recommend that, if adults with medication overuse headache are included in studies, they are stratified as part of the randomisation procedure.

The lack of preregistered studies was a limitation. From 1 July 2005, registration of studies of interventions has been mandatory, as part of the CONSORT process (Schulz 2010). We were unable to locate most study registrations and the vast majority of studies did not refer to a trial registry. This is likely because many studies were published before 2005. In addition, few studies nominated a primary outcome and there was little consensus about how to measure outcomes across studies (see measurement issues below). We rated the majority of studies at high risk of bias for performance bias, which is generally a problem in psychological trials where it is difficult to blind participants to conditions. It is possible to include attention placebo conditions and measure participants' treatment expectancy to try and ensure that there is a low risk of performance bias.

Measurement (end points)

There is a need for more conformity in the literature in terms of the outcomes that are measured. If psychological interventions are to be viewed as a primary intervention for the management of migraine, then they should be judged by the same criteria as other interventions (such as medications). There needs to be standardisation about which outcome measures are important. The results of this meta-analysis indicate that the field needs data on migraine intensity as none currently exists. This has been achieved in the rheumatology area with OMERACT, which is an initiative that organises consensus conferences biannually to agree on important outcomes that should be included in clinical trials (see Tugwell 2007 for a description of the initiative and its history), and through IMMPACT in chronic pain (Turk 2003). In the headache literature, Tassorelli 2018 has attempted to outline appropriate measures and time points for clinical trials for interventions to manage migraine. They make the following recommendations:

- baseline recording periods for adults with migraine should be at least 28 days of prospective recording, preferably electronically, where time stamps can confirm that participants are recording their headache features prospectively rather than retrospectively;
- the headache diary should include information on migraine-associated symptoms, migraine medication usage, duration (defined as how long the migraine persists), severity/intensity, whether an aura was present, and impact on daily functioning;
- primary outcomes and primary end points (e.g. end of treatment, follow-up) should be preregistered and prospectively defined. Primary outcomes should be either: change in number of headache days per month (and based on at least 28 days' monitoring), or change in number of headache days with moderate to severe migraine, or the proportion of participants whose migraine frequency reduces by 50% or more. In addition to the inclusion of each of these outcomes, they recommend the following secondary outcomes: migraine intensity, cumulative hours per month where migraine intensity is moderate to severe, conversion from chronic to episodic migraine (for chronic migraine), migraine medication usage, conversion of medication overuse to appropriate use (where relevant), depression, anxiety, functional impairment, and general impression of improvement;
- it is also important to record adverse events.

Transparency

Increasingly, it is being suggested that data should be made publicly available. Had we been able to obtain outcome data from each trial, this meta-analysis would have reported more comparisons and included additional data. This is particularly the case with headache diary data, where researchers captured but did not report means and standard deviations for key outcome data. Researchers should avail themselves of public repositories for their data so that they can be easily accessible and contribute to the evidence base.

It would be helpful for manuals or detailed summaries of interventions to be made available so that the content of interventions is clear. This would allow for work to be replicated. With the increase in publication of journals online, manuals or intervention summaries could be published as supplementary material, available through the journal's website.

There were some interventions that have been used in the literature, but no data were available for analysis in this review, so we were unable to draw conclusions about their effects. These included mindfulness and eye movement desensitisation and reprocessing. Future research should investigate novel interventions and compare them to other active treatments with some evidence of efficacy, such as behavioural approaches.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Bhombal 2014

Methods	RCT; 2 arms
Participants	Pretreatment: n = 110 2-week follow-up: n = 97, 4-week follow-up: n = 90 Sex: 72 F; 18 M (completers) Mean age (SD): treatment: 36.7 years (1.5); control: 34.6 years (1.8) Time since diagnosis: NR Migraine frequency: reported in graphical form only: 6 (control group) and 9 (treatment group) migraines/month Recruitment: outpatient clinics
Interventions	Treatment: pharmacotherapy plus behaviour management (n = 55) Control: pharmacotherapy alone (n = 55)
Outcomes	**Outcomes** assessed at pretreatment, 2-week and 4-week following treatment **Primary outcome** Migraine frequency: study authors measured the number of migraine attacks in a four-week period via a telephone interview (four weeks after treatment) **Secondary outcomes** Responder rate: none Migraine intensity: none Migraine duration: proportion of people who reported the average length of migraine as (a) < 6 h; (b) 6-12 h (c) 12-24 h and (d) > 24 h in a telephone interview Number of days with migraine per 4 weeks: none Mood: none Migraine medication usage: none Quality of life: an unspecified self-developed scale Migraine-related disability: none

Bhombal 2014 *(Continued)*

	Adverse events: none
Notes	Funding: NR COI: NR

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Statistician prepared concealed envelopes
Allocation concealment (selection bias)	Low risk	Concealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel not blinded
Blinding of outcome assessment (detection bias) All outcomes	High risk	Treating doctor conducted follow-up interview
Incomplete outcome data (attrition bias) All outcomes	High risk	90/110 available for assessment at 4 weeks; no ITT analysis
Selective reporting (reporting bias)	Unclear risk	Trial register not found
Treatment integrity	Low risk	Treatment standardised; no therapist involvement
Other bias	High risk	Sample size < 50 per arm

Bromberg 2012

Methods	RCT; 2 arms; assessed at pretreatment, 1-month, 3-month and 6-month follow-ups
Participants	Pretreatment: n = 189 1-month follow-up: n = 144, 3-month follow-up: n = 129, 6-month follow-up: n = 118 Sex: 165 F; 20 M Mean age (SD): treatment: 42.62 years (11.50) Time since diagnosis: 1 year Migraine frequency: NR; inclusion criteria required at least 2 migraines/month Recruitment: community and clinical advertisements
Interventions	Treatment: internet-based CBT + self-management (n = 94) Control: 'no treatment' control group (n = 95)

Bromberg 2012 *(Continued)*

Outcomes	Outcomes assessed at pretreatment, 1-month (post-treatment assessment), 3-month and 6-month follow-ups **Primary outcome** Migraine frequency: daily headache record over a 2-week period **Secondary outcomes** Responder rate: none Migraine intensity: none Migraine duration: daily headache record Number of days with migraine per 4 weeks: none Mood: Depression Anxiety and Stress Scales Migraine medication usage: none Quality of life: none Migraine-related disability: Migraine Disability Assessment Questionnaire Adverse events: reported 0 adverse events, but unclear whether these were assessed and how
Notes	Funding: "Grant support was received from the National Institutes of Health (NIH), the National Institute of Drug Abuse (NIDA No. R44DA023539-02)." COI: "All of the authors are employees of Inflexxion, Inc., Newton, MA."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Study staff created a randomisation table that contained 8 blocks (all combinations of the balancing factors; i.e. high pain/< 5 headaches/month/male, low pain/≥ 5 headaches/month/female). Used a random number table within each block to generate experimental/control assignments.
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and researchers were not blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No report of outcome blinding
Incomplete outcome data (attrition bias) All outcomes	High risk	55% of the intervention group completed the final assessment
Selective reporting (reporting bias)	Unclear risk	Trial register not found
Treatment integrity	Low risk	Treatment standardised; no therapist involvement

Bromberg 2012 *(Continued)*

Other bias	Unclear risk	Sample size between 50 and 199 per arm

Calhoun 2007

Methods	RCT; 2 arms; assessed at pretreatment and 6-week follow-up
Participants	Pretreatment: n = 43 6-week follow-up: n = 33 Sex: 43 F; 0 M Mean age (SD): treatment: 35.5 years (NR); control: 35.0 years (NR) Time since diagnosis: 11 years intervention group; 9.7 years placebo group Migraine frequency: 24.2 migraines/month in the treatment group; 23.2 migraines/month in the intervention group Recruitment: referral to academic medical centre
Interventions	Treatment: behavioural sleep modification (n = 23) Control: "placebo" behavioural modification (n = 20)
Outcomes	Outcomes assessed at pretreatment and 6 weeks following treatment **Primary outcome** Migraine frequency: headache diary (days with migraine > 4 weeks) **Secondary outcomes** Responder rate: reversion to "episodic migraine" Migraine intensity: headache diary Migraine duration: headache diary Number of days with migraine per 4 weeks: headache diary Mood: Beck Depression Inventory Migraine medication usage: none Quality of life: none Migraine-related disability: none Adverse events: none
Notes	Funding: "The authors acknowledge the National Headache Foundation for financial support of this project." COI: "Dr. Calhoun has worked for the Speakers Bureau of GlaxoSmithKline."

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Calhoun 2007 *(Continued)*

Random sequence generation (selection bias)	Low risk	Participants were randomised using random number tables
Allocation concealment (selection bias)	Unclear risk	Allocation concealment NR
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "All behavioral interventions were administered by the same instructor who was not blinded to the intervention."
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome assessment not blinded
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition was 14% in treatment group; 20% in control; no ITT analyses
Selective reporting (reporting bias)	Unclear risk	Trial register not found
Treatment integrity	High risk	Treatment standardised; therapist training NR
Other bias	High risk	Sample size < 50 per arm

Cousins 2015

Methods	RCT; 2 arms; assessed at pretreatment, post-treatment, 4-month follow-up
Participants	Pretreatment: n = 73 Post-treatment: n = 55, 4-month follow-up: n = 56 (53 for primary outcome) Sex: 60 F; 13 M Mean age (SD): treatment: 39 years (NR) Time since diagnosis: 6 months Migraine frequency: inclusion criteria was at least 3/month (average for treatment group = 11.78 (SD 7.67); control group = 11.54; SD 6.64)) Recruitment: specialist headache clinics
Interventions	Treatment: CBT + relaxation (n = 36) Control: standard medical care (n = 37)
Outcomes	Outcomes assessed at pretreatment, post-treatment, 4-month follow-up **Primary outcome** Migraine frequency: headache diary (4 weeks following treatment and at 4-month follow-up) **Secondary outcomes** Responder rate: headache diary

Cousins 2015 *(Continued)*

	Migraine intensity: headache diary Migraine duration: headache diary Number of days with migraine per 4 weeks: headache diary Mood: Hospital Anxiety and Depression Scales Migraine medication usage: headache diary Quality of life: EuroQol (EQ-5D) Migraine-related disability: Migraine Disability Assessment Adverse events: none
Notes	Funding: "This work was supported by the National Institute for Health Research (NIHR) under its Research for Patient Benefit (RfPB) Programme [Grant Reference Number PB-PG-0610-22373]." COI: "The authors declare no conflicts of interest."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was carried out using a web-based independent randomisation service provided by King's College London, Clinical Trials Unit
Allocation concealment (selection bias)	Low risk	Emails were automatically generated and sent to the researcher (blinded) confirming randomisation and to the therapist (unblinded) giving randomisation details.
Blinding of participants and personnel (performance bias) All outcomes	High risk	No equivalence of expectation due to standard care control
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Researcher remained blinded
Incomplete outcome data (attrition bias) All outcomes	High risk	28% attrition rate in treatment arm; no ITT analysis
Selective reporting (reporting bias)	Unclear risk	Trial register not found
Treatment integrity	Low risk	Standardised treatment; therapist training and supervision
Other bias	High risk	Sample size < 50 per arm

D'Souza 2008

Methods	RCT; 3 arms; assessed at baseline, 1-month and 3-month follow-up
Participants	Pretreatment: n = 90 1-month follow-up: n = 85, 3-month follow-up: n = 82

D'Souza 2008 *(Continued)*

	Sex: 80 F; 10 M Mean age (SD): 21.44 years (5.47) Time since diagnosis: NR Migraine frequency: 11.2 (SD 5.42) for relaxation; 9.94 (SD 7.22) for emotional disclosure; 9.65 (SD 6.64) for control Recruitment: undergraduate psychology students
Interventions	Treatment 1: relaxation therapy (n = 28) Treatment 2: written emotional disclosure (n = 31) Control: neutral writing condition (n = 31)
Outcomes	Outcomes assessed at baseline, 1-month and 3-months following treatment **Primary outcome** Migraine frequency: number of days with migraine in headache diary (4 weeks following treatment) **Secondary outcomes** Responder rate: none Migraine intensity: headache diary Migraine duration: none Number of days with migraine per 4 weeks: none Mood: none Migraine medication usage: none Quality of life: none Migraine-related disability: Migraine Disability Assessment Scale Adverse events: none
Notes	Funding: "Preparation of this manuscript was supported, in part, by a Clinical Science Award from the Arthritis Foundation, and by National Institutes of Health grants AR049059 and AG009203." COI: NR

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised (using a random numbers table) in blocks of 6
Allocation concealment (selection bias)	Low risk	Sealed packet containing instructions given to participants
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participant not blind to group assignment

D'Souza 2008 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Researchers were uninformed about participants' group assignments at follow-up
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition rate < 10%
Selective reporting (reporting bias)	Unclear risk	Trial register not found
Treatment integrity	Low risk	Standardised treatment; no therapist involvement
Other bias	High risk	Sample size < 50 per arm

Feuille 2015

Methods	RCT; 3 arms; assessed at pretreatment and 2 weeks post-treatment
Participants	Pretreatment: n = 107 Post-treatment: n = 74 Sex: 59 F; 13 M Mean age (SD): 19.9 years (3.5) Time since diagnosis: NR Migraine frequency: 5.9 (SD 4.3) migraines per month Recruitment: university campus and local community
Interventions	Treatment 1: standard mindfulness (n = 27) Treatment 2: spiritual mindfulness (n = 31) Control: relaxation training (n = 29)
Outcomes	Outcomes assessed at pretreatment and 2 weeks post-treatment **Primary outcome** Migraine frequency: diary (2 weeks) **Secondary outcomes** Responder rate: none Migraine intensity: retrospective report Migraine duration: none Number of days with migraine per 4 weeks: none Mood: none Migraine medication usage: none Quality of life: none

Feuille 2015 *(Continued)*

	Migraine-related disability: Headache Impact score Adverse events: none
Notes	Funding: "No funding external to the university." COI: NR

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Study authors created a chart listing each of the 3 conditions in this order — standard mindfulness, spiritual mindfulness or relaxation — repeatedly, in a counterbalanced order. Ahead of their arrival at the lab, research assistants wrote first names of participants arriving for the same appointment time slot into this chart alphabetically by first name
Allocation concealment (selection bias)	Low risk	Allocation concealed until time of treatment arrival
Blinding of participants and personnel (performance bias) All outcomes	Low risk	The control group informed to have similar expectations, and this was assessed
Blinding of outcome assessment (detection bias) All outcomes	High risk	Researchers were not blind to allocations
Incomplete outcome data (attrition bias) All outcomes	High risk	Participants were explicitly excluded if they had not completed 10/14 days of the migraine diary
Selective reporting (reporting bias)	Unclear risk	No protocol available
Treatment integrity	Unclear risk	Standardised treatments; therapist training NR
Other bias	High risk	Sample size < 50 per arm

Fritsche 2010

Methods	RCT; 2 arms; assessed at pretreatment, post-treatment (5 weeks), 3-month and 1-2-year follow-up (median 15.7 months)
Participants	Pretreatment: n = 158 Post-treatment: n = 146, 3-month follow-up: n = NR Sex: 136 F; 14 M Mean age (SD): treatment: 47.7 years (8.9), control: 48.2 years (10.1) Time since diagnosis: average 26.1 years (SD 12.9) for intervention group; 24.3 years (SD 11.6) for control Migraine frequency: 7.23 (SD 3.70) migraines/month for intervention; 7.27 (SD 3.82) for control

Fritsche 2010 *(Continued)*

	Recruitment: 70% recruited by advertisement, 30% recruited through co-operating medical practices
Interventions	Treatment: minimal contact CBT programme (n = 79) Control: bibliotherapy alone (n = 71)
Outcomes	Outcomes assessed at pretreatment, 5 weeks, 3-month and 1-2 years following treatment (median 15.7 months) **Primary outcome** Migraine frequency: headache diary (4 weeks following treatment) **Secondary outcomes** Responder rate: headache diary Migraine intensity: headache diary Migraine duration: headache diary Number of days with migraine per 4 weeks: headache diary Mood: Hospital Anxiety and Depression Scale Migraine medication usage: headache diary Quality of life: none Migraine-related disability: headache diary Adverse events: none
Notes	Funding: "The study was supported by the German Ministry of Research and Education Grant (BMBF) (O1EM0513)." COI: "There are no conflicts of interest associated with this study."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were centrally randomised to 1/2 treatment arms using the BiAS programme
Allocation concealment (selection bias)	Unclear risk	Allocation concealment NR
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and researchers were not blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Assessor blinding was NR
Incomplete outcome data (attrition bias) All outcomes	High risk	76% total attrition; no ITT analysis

Fritsche 2010 *(Continued)*

Selective reporting (reporting bias)	Unclear risk	Trial register not found
Treatment integrity	Low risk	Standardised treatment provided to participants; therapist trained in treatment
Other bias	Unclear risk	Sample size between 50 and 199 per arm

Hedborg 2011

Methods	RCT; 3 arms; assessed at baseline/pretreatment (0 months and 2 months), and 5 months, 8 months, 11 months after initial baseline
Participants	Baseline: n = 83, pretreatment: n = 76 Post-treatment: n = 71, 8 months: n = 71, 11 months: n = 71 Sex: 52 F; 24 M Mean age (SD): hand massage + MBT: 49.4 years (NR), extended baseline MBT: 44.8 years (NR), controls: 49.0 years (NR) Time since diagnosis: 23.1 years for hand massage plus MBT; 22.2 years for MBT; and 24.3 years for controls Migraine frequency: at least 2 migraines/month required for inclusion Recruitment: advertisement
Interventions	Treatment 1: internet-delivered MBT programme + hand massage (n = 25) Treatment 2: internet-delivered MBT programme (n = 24) Control: inactive control (n = 27)
Outcomes	Outcomes assessed before treatment and 2 months, 5 months, 8 months and 11 months after initial baseline **Primary outcome** Migraine frequency: diary (2 months) **Secondary outcomes** Responder rate: diary Migraine intensity: diary Migraine duration: diary Number of days with migraine per 4 weeks: diary Mood: Montgomery-Åsberg Depression Rating Scale Migraine medication usage: headache diary reported in Hedborg & Muhr, 2012 (see Hedborg 2011) Quality of life: PQ23 Migraine-related disability: none Adverse events: none

Hedborg 2011 *(Continued)*

Notes	Funding: "We are grateful for: financial support from the Erik, Karin, and Gösta Selander Foundation and from the Nursing Research Foundation, Faculty of Medicine and Pharmacy, Uppsala University." COI: "The authors report no conflicts of interest."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was through random number generation in SPSS
Allocation concealment (selection bias)	Unclear risk	Allocation concealment NR
Blinding of participants and personnel (performance bias) All outcomes	High risk	An active control group was used to balance expectation; but personnel were not blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The randomisation process was blinded to the investigators
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition < 10%
Selective reporting (reporting bias)	Unclear risk	Trial register not found
Treatment integrity	High risk	Standardised online treatment; (hand massage) therapists not appropriately qualified
Other bias	High risk	Sample size < 50 per arm

Holroyd 2010

Methods	RCT; 4 arms; assessed at pretreatment, 5-month, 10-month and 16-month follow-up
Participants	Pretreatment: n = 232 Post-treatment: n = 176, 10-month follow-up: n = 151, 16-month follow-up: n = 118 Sex: 184 F; 48 M Mean age (SD): 38.2 years (10.2) Time since diagnosis: NR Migraine frequency: inclusion criteria: at least 3 migraines/month. Average for sample: 5.5 migraines/month (SD 1.9) Recruitment: physician referrals and local advertisements
Interventions	Treatment: behavioural management with beta-blocker (n = 69) Behavioural management with placebo (n = 55)

Holroyd 2010 *(Continued)*

	Control: beta-blocker alone (n = 53) Placebo alone (n = 55)
Outcomes	Outcomes assessed before treatment, 5-month, 10-month and 16-month follow-up **Primary outcome** Migraine frequency: migraine diary (number of days with migraine) for 30 days following treatment **Secondary outcomes** Responder rate: migraine diary Migraine intensity: none Migraine duration: none Number of days with migraine per 4 weeks: migraine diary Mood: none Migraine medication usage: none Quality of life: migraine-specific quality of life, reported in Seng & Holroyd 2010 (see Holroyd 2010) Migraine-related disability: none Adverse events: proportion of participants reporting side-effects
Notes	Funding: "Grant R01-NS-32374 (awarded to KAH) from the National Institutes of Health provided primary support for this trial. Merck Pharmaceuticals and GlaxoSmithKline Pharmaceuticals donated triptans for the trial, which was their only involvement." COI: "KAH has consulted for ENDO Pharmaceuticals and for Takeda Pharmaceuticals North America and received an investigator initiated grant from ENDO Pharmaceuticals. He has also received support from the National Institutes of Health (NINDS; NS32375). CKC has received research funding and materials from GlaxoSmithKline Pharmaceuticals (GSK) and Merck and participates in industry sponsored research involving GSK, Merck, UCB Pharma, and Allergan. FJO'D has received research funding and materials from GSK and Merck; receives educational funding from GSK, Merck, and Allergan; participates in industry sponsored research involving GSK, Merck, UCB Pharma, and Allergan; and has consulted for and received honorariums from GSK. GEC owns stock in Johnson and Johnson, Novartis, and Wyeth Pharmaceuticals."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A statistician not otherwise connected with the study generated the randomisation sequence by computer
Allocation concealment (selection bias)	Low risk	Randomisation schedule was supplied in sealed, opaque envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	For the placebo both participants and researchers were double-blind; however, neither participants nor researchers were blinded for behavioural management group
Blinding of outcome assessment (detection bias) All outcomes	High risk	Neither participants nor researchers were blinded for behavioural management group

Holroyd 2010 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	High risk	Although ITT analyses were used, attrition by 16 month follow-up was very high (approximately 50%)
Selective reporting (reporting bias)	Low risk	Trial registry matches outcomes and design
Treatment integrity	Low risk	Therapists specifically trained; supervision received; treatment fidelity checks
Other bias	Unclear risk	Sample size between 50 and 199 per arm

Kang 2009

Methods	RCT; 2 arms; assessed at pretreatment, and 2 weeks and 4 weeks following treatment
Participants	Pretreatment: n = 32 Post-treatment: 2 weeks: n = 32, 4 weeks n = NR Sex: 32 F; 0 M Mean age (SD): treatment: n = 31.12 years (5.49), monitoring control: n = 31.87 years (4.70) Time since diagnosis: for treatment group, 9 years (SD 5.86); control group 8.6 years (SD 5.70) Migraine frequency: NR Recruitment: advertisement
Interventions	Treatment: biofeedback (n = 17) Control: monitoring (n = 15)
Outcomes	Outcomes assessed at pretreatment, and 2 weeks and 4 weeks following treatment **Primary outcome** Migraine frequency: headache diary (7 days) **Secondary outcomes** Responder rate: headache diary Migraine intensity: none Migraine duration: none Number of days with migraine per 4 weeks: none Mood: Hamilton Depression Scale Migraine medication usage: none Quality of life: none Migraine-related disability: none Adverse events: none
Notes	Funding: "This study was supported by a grant from the Korea Health Industry Development Institute and the Ministry of Health and Welfare (02-PJ1-PG1-CH05-0003)."

Kang 2009 *(Continued)*

	COI: NR

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The method of random sequence generation NR
Allocation concealment (selection bias)	Unclear risk	Allocation concealment NR
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and researchers were not blind
Blinding of outcome assessment (detection bias) All outcomes	High risk	Researchers were not blind
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No attrition data were reported
Selective reporting (reporting bias)	Unclear risk	Trial registry not found
Treatment integrity	High risk	Therapist training and treatment fidelity NR
Other bias	High risk	Sample size < 50 per arm

Kaushik 2005

Methods	RCT; 2 arms; assessed before treatment, 6 months and 1 year after treatment commenced
Participants	Pretreatment: n = 192 Post-treatment: n = 167, 1-year follow-up: n = 126 Sex: 132 F; 60 M Mean age (SD): NR Time since diagnosis: NR Migraine frequency: at least 4 migraines/month inclusion criteria; 69% had between 4 and 5 migraines/month; 27% had > 5 Recriutment: headache clinic
Interventions	Treatment: biofeedback + relaxation (n = 96) Control: propanalol (n = 96)
Outcomes	Outcomes assessed before treatment, 6 months and 1 year after treatment commenced **Primary outcome**

Kaushik 2005 *(Continued)*

	Migraine frequency: daily diary time frame not specified **Secondary outcomes** Responder rate: none Migraine intensity: daily diary Migraine duration: daily diary Number of days with migraine per 4 weeks: daily diary Mood: none Migraine medication usage: daily diary Quality of life: none Migraine-related disability: none Adverse events: percentage of participants with adverse events
Notes	Funding: "We are grateful to the Presidential body of the Himalayan Institute Hospital Trust, Dehradun, India, for funding this project." COI: NR

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Generated by a "senior observer", stratified for type of headache (with and without aura)
Allocation concealment (selection bias)	Low risk	Sealed, opaque envelopes concealed allocation
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants expected benefit in each arm and assessors were blinded. However, participants may not have expected continued benefit after tapering the pharmacotherapy, leading to a high risk of bias at follow-up.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessors were blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	13% attrition rate, but ITT analysis conducted
Selective reporting (reporting bias)	Unclear risk	No protocol described
Treatment integrity	High risk	Therapist training and treatment fidelity NR
Other bias	Unclear risk	Sample size between 50 and 199 per arm

Kleiboer 2014

Methods	RCT; 2 arms; assessed at pretreatment, post-treatment and 6-month follow-up
Participants	Pretreatment: n = 368 Post-treatment: n = 363, 6-month follow-up: n = 280 Sex: 314 F; 54 M Mean age (SD): 43.6 years (11.5) Time since diagnosis: 21.9 years (SD 13) Migraine frequency: inclusion criteria required 2-6 attacks/month; 54% had 2-3 migraines/month; 46% had 4-6 migraines/month Recriutment: referral from headache specialists
Interventions	Treatment: online behavioural training (n = 195) Control: waiting-list control (n = 173)
Outcomes	Outcome assessed at before treatment, after treatment and at 6-month follow-up **Primary outcome** Migraine frequency: headache diary for 30 days **Secondary outcomes** Responder rate: none Migraine intensity: headache diary Migraine duration: none Number of days with migraine per 4 weeks (NB: 30 days): headache diary Mood: none Migraine medication usage: none Quality of life: Migraine-specific Quality of Life Migraine-related disability: Migraine Disability Assessment Scale Adverse events: none
Notes	Funding: "This study was supported by grant # 1871 of the Health Insurers Innovation Foundation (Innovatiefonds Zorgverzekeraars) and by substantial support of the Utrecht University Faculty of Social and Behavioral Sciences." COI: NR

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-derived randomisation scheme
Allocation concealment (selection bias)	Low risk	Allocation was done by a research assistant who was unaware of the next study group assignment

Kleiboer 2014 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "Blinding was not possible because the study concerns a psychological intervention"
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "Blinding was not possible because the study concerns a psychological intervention"
Incomplete outcome data (attrition bias) All outcomes	High risk	Approx 30% attrition rate in intervention arm at follow-up, but ITT analysis conducted
Selective reporting (reporting bias)	Unclear risk	Trial registry not found
Treatment integrity	Low risk	Standardised online treatment; therapists supervised
Other bias	Unclear risk	Sample size between 50 and 199 per arm

Kohlenberg 1981

Methods	RCT; 2 arms; assessed at pretreatment and 3-month and 6-month follow-up
Participants	Pretreatment: n = 117 3-month follow-up: n = 51, 6-month follow-up: n = 51 Sex: 116 F; 1 M Mean age (SD): treatment: 46.7 years (NR), control: 44 years (NR) Time since diagnosis: NR Migraine frequency: inclusion criteria required at least 2 migraines/month; average presented in graphical form approximately 2 migraines/week Recriutment: advertisement
Interventions	Treatment: self-help book focused on temperature biofeedback (n = 58) Control: control book *More Than Two Aspirin* (n = 59)
Outcomes	Outcomes assessed before treatment and 3 months and 6 months following intervention **Primary outcome** Migraine frequency: headache diary (4 weeks) **Secondary outcomes** Responder rate: none Migraine intensity: headache diary Migraine duration; headache diary Number of days with migraine per 4 weeks: headache diary Mood: none

Kohlenberg 1981 *(Continued)*

	Migraine medication usage: headache diary
	Quality of life: none
	Migraine-related disability: none
	Adverse events: none
Notes	Funding: NR
	COI: NR

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation NR
Allocation concealment (selection bias)	Unclear risk	Allocation concealment NR
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Although expectancy was controlled for and equivalent, the researchers blinding was NR
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment was NR
Incomplete outcome data (attrition bias) All outcomes	High risk	> 50% of participants were lost to attrition, no ITT conducted
Selective reporting (reporting bias)	Unclear risk	Trial published prior to registers
Treatment integrity	Low risk	Standardised treatment manual; no therapist
Other bias	High risk	Sample size < 50 per arm

Mahmoudzadeh-Zarandi 2016

Methods	RCT; 2 arms; assessed at pre- and post-treatment
Participants	Pretreatment: n = 88
	Post-treatment: n = 83
	Sex: 61 F; 22 M
	Mean age (SD): NR
	Time since diagnosis: NR
	Migraine frequency: at least 5 migraines/month inclusion criteria; means NR

Mahmoudzadeh-Zarandi 2016 *(Continued)*

	Recruitment: neurology clinic
Interventions	Treatment: "Orem's self-care" behavioural programme (n = 44) Control: treatment as usual (n = 44)
Outcomes	Oucomes assessed before and after treatment **Primary outcome** Migraine frequency: none **Secondary outcomes** Responder rate: none Migraine intensity: none Migraine duration: none Number of days with migraine per 4 weeks: none Mood: none Migraine medication usage: none Quality of life: none Migraine-related disability: Migraine Disability Assessment Scales Adverse events: none
Notes	Funding: NR COI: "The authors declare no conflict of interest in this study."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation method NR
Allocation concealment (selection bias)	Unclear risk	Allocation concealment NR
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel not blind, expectancies not compared
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment NR
Incomplete outcome data (attrition bias) All outcomes	Low risk	6% attrition rate
Selective reporting (reporting bias)	Unclear risk	No registry entry identified

Mahmoudzadeh-Zarandi 2016 *(Continued)*

Treatment integrity	High risk	Therapist training and treatment fidelity NR
Other bias	High risk	Sample size < 50 per arm

Marcus 2008

Methods	RCT; 2 arms; assessed at pretreatment, post-treatment, 24 h, 48 h, and 7 days
Participants	Pretreatment: n = 52 Post-treatment: n = 43, 24 h: n = 43, 48 h: n = 43, 7 days: n = 43 Sex: 50 F; 2 M Mean age (SD): treatment: 38.33 years (10.57), control: 37.95 years (9.57) Time since diagnosis: 12.5 years Migraine frequency: NR in either inclusion criteria nor demographic data Recruitment: hospital neurology, emergency and medical departments
Interventions	Treatment: eye movement desensitisation and reprocessing (n = 26) Control: standard medical care (n = 26)
Outcomes	Outcomes assessed at before and after intervention, 24 h, 48 h, and 7 days following intervention **Primary outcome** Migraine frequency: headache diary (7 days) **Secondary outcomes** Responder rate: headache diary Migraine intensity: headache diary Migraine duration: headache diary Number of days with migraine per 4 weeks: none Mood: none Migraine medication usage: none Quality of life: none Migraine-related disability: Migraine Disablity Assessment Scale Adverse events: zero adverse events reported in the intervention group, no report of adverse events in the control group (who also received medication)
Notes	Funding: NR COI: NR

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Marcus 2008 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Randomisation details NR
Allocation concealment (selection bias)	Unclear risk	Allocation concealment NR
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants were not blind and the expectations were not equivalent between the groups
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessor was independent of treatment and blinded
Incomplete outcome data (attrition bias) All outcomes	High risk	18% attrition rate; no ITT analysis and removal of outlier for non-response
Selective reporting (reporting bias)	Unclear risk	No trial registry could be identified
Treatment integrity	Low risk	Treatment fidelity assessments and therapist training
Other bias	High risk	Sample size < 50 per arm

Meyer 2016

Methods	RCT; 2 arms; assessed at pretreatment, post-treatment, and 3-month follow-up
Participants	Pretreatment: n = 52 Post-treatment: n = 35, 3-month follow-up: n = 35 Sex: 31 F; 4 M Mean age (SD): treatment: 36.4 years (NR), control: 33.8 years (NR) Time since diagnosis: 11.4 years for intervention group; 11.3 for waiting-list Migraine frequency: 5.5 migraines/month treatment group; 5.79 migraines/month waiting-list Recruitment: advertisement
Interventions	Treatment: progressive muscle relaxation (n = 16) Control: waiting list (n = 19)
Outcomes	Outcomes assessed before and after treatment and 3-month follow-up **Primary outcome** Reduction in migraine frequency: headache diary for 1 month following treatment **Secondary outcomes** Responder rate: none Migraine intensity: none

Meyer 2016 *(Continued)*

	Migraine duration: none Number of days with migraine per 4 weeks: number of days/month with migraine Mood: none Migraine medication usage: none Quality of life: none Migraine-related disability: none Adverse events: none
Notes	Funding: "The study was supported by a grant from the German Migraine and Headache Society (Deutsche Migräne- und Kopfschmerzgesellschaft, DMKG)." COI: "The authors declare that they have no competing interests."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quasi-randomisation reported
Allocation concealment (selection bias)	Unclear risk	Allocation concealment NR
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and researchers not blind
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "data analysis was blinded."
Incomplete outcome data (attrition bias) All outcomes	High risk	21% attrition rate; no ITT analysis conducted
Selective reporting (reporting bias)	Unclear risk	No trial registry found
Treatment integrity	High risk	Therapist training and treatment fidelity NR
Other bias	High risk	Sample size < 50 per arm

Mérelle 2008

Methods	RCT; 2 arms, assessed at pretreatment and post-treatment
Participants	Pretreatment: n = 129 Post-treatment: n = 108 Sex: 94 F; 14 M

Mérelle 2008 *(Continued)*

	Mean age (SD): 44 years (NR) Time since diagnosis: 19 years (range 2-50) Migraine frequency: exclusion criterion was > 15 migraines/month; 65% had 1-3 migraines/month; 35% had 4-6 migraines/month Recriutment: Dutch Society of Headache Patients, multimedia, and headache specialists
Interventions	Treatment: behavioural training (n = 51) Contol: waiting-list control (n = 57)
Outcomes	**Primary outcome** Migraine frequency: headache diary (4 weeks following treatment) **Secondary outcomes** Responder rate: % with 50% reduction in migraines Migraine intensity: diary (rated every 6 h for 4 weeks) - averaged pain intensity over the 4 weeks Migraine duration: none Number of days with migraine per 4 weeks: headache diary Mood: none Migraine medication usage: diary Quality of life: Migraine specific QOL Migraine-related disability: Migraine Disability Assessment Scale Adverse events: none
Notes	Funding: The project was supported by grant no. 940-31-069 from the Netherlands Organization for Health Research and Development (ZonMw), The Hague and financial means provided by the Pain Expertise Centre Rotterdam. COI: NR

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised according to a random number table, performed by a statistician
Allocation concealment (selection bias)	Unclear risk	Allocation concealment NR
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and researchers were not blind
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome measures blinded by research assistant prior to analysis

Mérelle 2008 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	< 10% attrition
Selective reporting (reporting bias)	Unclear risk	Trial register not found
Treatment integrity	High risk	Training run by lay people, not appropriately qualified therapists
Other bias	Unclear risk	Sample size between 50 and 199 per arm

Rashid-Tavalai 2016

Methods	RCT, 2 arms; assessed at pretreatment and post-treatment
Participants	Pretreatment: n = 40 Post-treatment: n = 35 Sex: 28 F; 7 M Mean age: NR Time since diagnosis: 3 months minimum Migraine frequency: at least 15 days/month inclusion criteria; means NR Recruitment: neurological clinics
Interventions	Treatment: coping skills training plus pharmacotherapy (n = 20) Control: pharmacotherapy alone (n = 20)
Outcomes	Outcomes assessed at before and after treatment. **Primary outcome** Reduction in migraine frequency: none **Secondary outcomes** Responder rate: none Migraine intensity: Migraine Headache Index Migraine duration: none Number of days with migraine per 4 weeks: none Mood: none Migraine medication usage: none Quality of life: World Health Quality of Life Instrument Migraine-related disability: none Adverse events: none
Notes	Funding: "The present research (as a thesis) was supported in part by Zahedan University of Medical Sciences."

Rashid-Tavalai 2016 *(Continued)*

COI: "The authors declare that there is no conflict of interests regarding the publication of this paper."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Random sequence generation unclear
Allocation concealment (selection bias)	Unclear risk	Allocation concealment NR
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel not blind
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment NR
Incomplete outcome data (attrition bias) All outcomes	High risk	12.5% attrition rate; no ITT analysis conducted
Selective reporting (reporting bias)	Unclear risk	No protocol identified or referred to
Treatment integrity	High risk	Therapist training and treatment fidelity NR
Other bias	High risk	Sample size < 50 per arm

Richardson 1989

Methods	RCT; 3 arms; assessed at pretreatment, post-treatment, 6-month follow-up
Participants	Pretreatment: n = 51 Post-treatment: n = 47, 6-month follow-up: n = 43 Sex: 30 F; 7 M Mean age: treatment 1: 34.4 years (NR), treatment 2: 34.4 years (NR), control: 38.0 years (NR) Time since diagnosis: 3 months; treatment 1: 16.5 (4-34); treatment 2: 18 (3-35); control: 15.6 (range 2-40); Migraine frequency: at least 2 migraines/month inclusion criteria; means NR Recruitment: advertisements, public health nurses, and physicians
Interventions	Treatment 1: clinic-based CBT programme (n = 15) Treatment 2: minimal therapist-contact format (n = 15) Control: waiting list (n = 17)
Outcomes	Outcomes assessed at before and after treatment and at 6-month follow-up

Richardson 1989 *(Continued)*

	Primary outcome Reduction in migraine frequency: headache diary (4 weeks following treatment) **Secondary outcomes** Responder rate: none Migraine intensity: headache diary Migraine duration: headache diary Number of days with migraine per 4 weeks: headache diary Mood: none Migraine medication usage: headache diary Quality of life: none Migraine-related disability: none Adverse events: none
Notes	Funding: "This research was supported in part by a grant from The National Headache Foundation and by a Medical Research Council of Canada Studentship to G. M. Richardson. Dr. P. J. McGrath is supported by a Career Scientist Award of the Ontario Ministry of Health." COI: NR

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation details NR
Allocation concealment (selection bias)	Unclear risk	Allocation concealment NR
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of personnel and participants NR
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment NR
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Attrition rates NR
Selective reporting (reporting bias)	Unclear risk	No trial registry identified
Treatment integrity	High risk	Therapist training and treatment fidelity NR
Other bias	High risk	Sample size < 50 per arm

Rothrock 2006

Methods	RCT; 2 arms; assessed at pretreatment, 1-month, 3-month, and 6-month follow-up
Participants	Pretreatment: n = 100 Follow-up: n = 100, 3-month follow-up: n = 100, 6-month follow-up: n = 100 Sex: 92 F; 8 M Mean age (SD): 42.5 years (NR) Time since diagnosis: NR Migraine frequency: 19% < 15/month; 50%: > 15 migraines/month; 31% chronic daily migraine Recruitment: university-based headache clinic
Interventions	Treatment: course on migraine biogenesis and management (n = 50) Control: inactive control (n = 50)
Outcomes	Outcomes assessed before treatment, after treatment and at 3-month, and 6-month follow-up **Primary outcome** Reduction in migraine frequency: headache diary for 1 month following treatment **Secondary outcomes** Responder rate: none Migraine intensity: headache diary Migraine duration: none Number of days with migraine per 4 weeks: headache diary Mood: none Migraine medication usage: headache diary Quality of life: none Migraine-related disability: Migraine Disability Assessment Scale Adverse events: none
Notes	Funding: NR COI: NR

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation details NR
Allocation concealment (selection bias)	Unclear risk	Allocation concealment NR

Rothrock 2006 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants not blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Neurologist was blinded to allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	< 10% attrition
Selective reporting (reporting bias)	Unclear risk	Trial published prior to registration
Treatment integrity	High risk	Treatment fidelity NR
Other bias	Unclear risk	Sample size between 50 and 199 per arm

Sargent 1986

Methods	RCT; 4 arms; assessed pretreatment and post-treatment
Participants	Pretreatment: n = 193 Post-treatment: n = 136 Sex: 114 F; 22 M Mean age (SD): 35.7 years (NR) Time since diagnosis: 2 years Migraine frequency: inclusion criteria at least 4 migraines/month; 6.78 migraines/month Recruitment: referred by physicians (60%) or self-referred (40%)
Interventions	Treatment 1: autogenic phrases Treatment 2: EMG biofeedback Treatment 3: thermal biofeedback Control: no treatment
Outcomes	Outcomes assessed before and after treatment **Primary outcome** Reduction in migraine frequency: headache diary (4 weeks) **Secondary outcomes** Responder rate: none Migraine intensity: headache diary Migraine duration: headache diary

Sargent 1986 *(Continued)*

	Number of days with migraine per 4 weeks: none Mood: none Migraine medication usage: headache diary Quality of life: World Health Quality of Life Instrument Migraine-related disability: single item related to migraine Adverse events: none
Notes	Funding: "This work was supported by Grant MH26026 from the National Institute of Mental Health and by grants from the National Migraine Foundation and the P. W. Skogmo Foundation." COI: NR

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The project secretary used a set of random numbers prepared at the beginning of the study (from a table)
Allocation concealment (selection bias)	Low risk	The project secretary had no knowledge of the participant's clinical history
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of personnel and participants NR
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment NR
Incomplete outcome data (attrition bias) All outcomes	High risk	30% attrition rate, no ITT analysis conducted
Selective reporting (reporting bias)	Unclear risk	Trial published prior to registration
Treatment integrity	High risk	Treatment fidelity and therapist training NR
Other bias	High risk	Sample size < 50 per arm

CBT: cognitive behaviour therapy; **COI:** conflict of interest; **EMG:** electromyography; **EQ-5D:** EuroQol health-related quality of life; **F:** female; **h:** hour(s); **ITT:** intention to treat; **M:** male; **MBT:** multimodal behavioural treatment; **NR:** not recorded; **QOL:** quality of life; **PQ23:** Quality of Life Questionnaire; **RCT:** randomised controlled trial; **SD:** standard deviation; **SPSS:** Statistical Processing for the Social Sciences

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Anderson 1975	Inadequate sample for inclusion (included children < 18 in sample)
Andersson 2003	Inadequate sample size (n < 15 in at least 1 arm of study design)

Study	Reason for exclusion
Andreychuk 1975	Inadequate sample size (n < 15 in at least 1 arm of study design)
Attfield 1979	Inadequate sample size (n < 15 in at least 1 arm of study design)
Bakhshani 2016	Inadequate study design (migraine data not separated from other headache conditions)
Basler 1996	Inadequate study design (migraine data not separated from other headache conditions)
Bild 1980	Inadequate sample size (n < 15 in at least 1 arm of study design)
Blanchard 1978	Inadequate sample size (n < 15 in at least 1 arm of study design)
Blanchard 1985	Inadequate study design (not RCT: no control group)
Blanchard 1990a	Inadequate study design (migraine data not separated from other headache conditions)
Blanchard 1990b	Inadequate sample size (n < 15 in at least 1 arm of study design)
Blanchard 1991	Inadequate sample size (n < 15 in at least 1 arm of study design)
Blanchard 1997	Inadequate study design (migraine data not separated from other headache conditions)
Brown 1984	Inadequate sample size (n < 15 in at least 1 arm of study design)
Cooper 2016	Inadequate study design (not RCT: commentary)
Daly 1983	Inadequate sample size (n < 15 in at least 1 arm of study design)
Devineni 2005	Inadequate sample size (n < 15 in at least 1 arm of study design)
Dindo 2014	Inadequate sample size (n < 15 in at least 1 arm of study design)
Dittrich 2008	Inadequate study design (insufficient psychotherapeutic content)
Doerr-Proske 1985	Inadequate sample size (n < 15 in at least 1 arm of study design)
Gerber 1985	Inadequate study design (not RCT: cross-over study)
Gerhards 1985	Inadequate sample size (n < 15 in at least 1 arm of study design)
Grazzi 2002	Inadequate sample size (n < 15 in at least 1 arm of study design)
Grazzi 2016	Conference abstract only and no full report of the trial available
Grazzi 2017	Inadequate study design (not RCT)
Grigorieva 2003	Non-English paper; unable to locate paper, study authors did not respond to requests for data
Guang'an 2001	Non-English paper; unable to locate paper, study authors did not respond to requests for data
Haag 1987	Inadequate sample size (n < 15 in at least 1 arm of study design)
Hart 1984	Inadequate sample size (n < 15 in at least 1 arm of study design)
Hoffmann 2008	Inadequate study design (insufficient psychotherapeutic content)

Study	Reason for exclusion
Holroyd 1988	Inadequate study design (migraine data not separated from other headache conditions)
Holroyd 1989	Inadequate sample size (n < 15 in at least 1 arm of study design)
Holroyd 1995	Inadequate sample size (n < 15 in at least 1 arm of study design)
Jurish 1983	Inadequate sample size (n < 15 in at least 1 arm of study design)
Lambley 1978	Inadequate sample size (n < 15 in at least 1 arm of study design)
Lemstra 2002	Inadequate study design (insufficient psychotherapeutic content)
Main 2002	Inadequate sample size (n < 15 in at least 1 arm of study design)
Martin 1989	Inadequate study design (migraine data not separated from other headache conditions)
Martin 2014	Inadequate study design (migraine data not separated from other headache conditions)
Martin 2015	Inadequate study design (not RCT: commentary)
Martin 2017	Conference abstract only and no full report of the trial available
Mitchell 1971	Inadequate sample size (n < 15 in at least 1 arm of study design)
Mizener 2004	Dissertation only and no full report of the trial available
Mullally 2001	Conference abstract only and no full report of the trial available
Mullally 2009	Inadequate study design (migraine data not separated from other headache conditions)
Mullinix 1978	Inadequate sample size (n < 15 in at least 1 arm of study design)
Nasiri 2016	Non-English paper; unable to locate paper and study authors did not respond to requests for data
Philips 1977	Inadequate sample size (n < 15 in at least 1 arm of study design)
Reading 1984	Inadequate sample size (n < 15 in at least 1 arm of study design)
Safarinia 2015	Non-English paper; unable to locate paper and study authors did not respond to requests for data
Sharma 2010	Conference abstract only and no full report of the trial available
Smitherman 2016	Inadequate sample size (n < 15 in at least 1 arm of study design)
Sorbi 2011	Conference abstract only and no full report of the trial available
Stout 1985	Inadequate sample size (n < 15 in at least 1 arm of study design)
Trinka 2002	Inadequate sample size (n < 15 in at least 1 arm of study design)
Varkey 2010	Conference abstract only and no full report of the trial available
Voerman 2014	Inadequate study design (follow-up study with no comparison data)
Wachholtz 2008	Inadequate study design (migraine data not separated from other headache conditions)

Study	Reason for exclusion
Wang 2005	Inadequate sample for inclusion (included children < 18 in sample)
Warner 1975	Inadequate sample size (n < 15 in at least 1 arm of study design)
Williamson 1984	Inadequate sample size (n < 15 in at least 1 arm of study design)
Wober 2009	Conference abstract only and no full report of the trial available
Wojciechowski 1984	Inadequate sample for inclusion (primary pain presentation not migraine)
Wylie 1997	Inadequate sample size (n < 15 in at least 1 arm of study design)

n: number of participants; **RCT:** randomised controlled trial

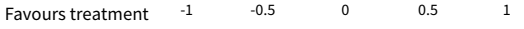
DATA AND ANALYSES

Comparison 1. Therapy versus control (post-treatment)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Reduction in migraine frequency:	4	681	Std. Mean Difference (IV, Random, 95% CI)	-0.02 [-0.17, 0.13]
2 Responder rate (achievement of at least 50% reduction in migraine frequency)	4	338	Risk Ratio (M-H, Random, 95% CI)	2.21 [1.63, 2.98]
3 Migraine intensity	4	685	Std. Mean Difference (IV, Random, 95% CI)	-0.13 [-0.28, 0.02]
4 Migraine medication usage	2	483	Std. Mean Difference (IV, Random, 95% CI)	-0.06 [-0.35, 0.24]
5 Mood	4	432	Mean Difference (IV, Fixed, 95% CI)	0.08 [-0.33, 0.49]
6 Quality of life	4	565	Std. Mean Difference (IV, Random, 95% CI)	-0.02 [-0.30, 0.26]
7 Migraine-related disability	6	952	Std. Mean Difference (IV, Random, 95% CI)	-0.67 [-1.34, 0.00]
8 Adverse events	2	208	Risk Ratio (M-H, Random, 95% CI)	0.16 [0.00, 7.85]

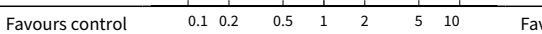
Analysis 1.1. Comparison 1 Therapy versus control (post-treatment), Outcome 1 Reduction in migraine frequency:.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
D'Souza 2008	28	9.4 (6.1)	15	9 (6.1)		5.83%	0.06[-0.56,0.69]
D'Souza 2008	31	9 (5.8)	16	9 (6.1)		6.31%	0[-0.6,0.61]
Fritsche 2010	60	5.6 (3.8)	55	5.8 (4)		17.15%	-0.05[-0.41,0.32]
Kleiboer 2014	195	2.8 (2)	173	2.7 (1.7)		54.77%	0.05[-0.15,0.26]
Mérelle 2008	51	2.4 (1.7)	57	2.9 (1.7)		15.94%	-0.27[-0.65,0.11]
Total ***	**365**		**316**			**100%**	**-0.02[-0.17,0.13]**
Heterogeneity: Tau^2=0; Chi^2=2.2, df=4(P=0.7); I^2=0%							
Test for overall effect: Z=0.22(P=0.83)							



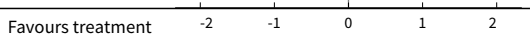
Analysis 1.2. Comparison 1 Therapy versus control (post-treatment), Outcome 2 Responder rate (achievement of at least 50% reduction in migraine frequency).

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Hedborg 2011	10/24	2/13		4.91%	2.71[0.7,10.55]
Hedborg 2011	10/25	2/12		4.96%	2.4[0.62,9.29]
Holroyd 2010	53/69	19/55		60.85%	2.22[1.51,3.27]
Kang 2009	10/17	3/15		7.67%	2.94[0.99,8.73]
Mérelle 2008	18/51	11/57		21.61%	1.83[0.96,3.5]
Total (95% CI)	**186**	**152**		**100%**	**2.21[1.63,2.98]**
Total events: 101 (Treatment), 37 (Control)					
Heterogeneity: Tau^2=0; Chi^2=0.7, df=4(P=0.95); I^2=0%					
Test for overall effect: Z=5.15(P<0.0001)					



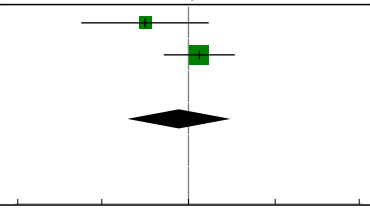
Analysis 1.3. Comparison 1 Therapy versus control (post-treatment), Outcome 3 Migraine intensity.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
D'Souza 2008	28	4.7 (2.1)	15	5.6 (1.7)		5.68%	-0.43[-1.06,0.21]
D'Souza 2008	31	5.2 (2.3)	16	5.6 (1.7)		6.26%	-0.15[-0.75,0.45]
Kaushik 2005	96	1.8 (1.1)	96	2 (1)		28.47%	-0.13[-0.42,0.15]
Kleiboer 2014	195	6.2 (1.8)	173	6.4 (1.7)		54.4%	-0.11[-0.32,0.09]
Rashid-Tavalai 2016	18	6.8 (2.3)	17	6.7 (2.8)		5.2%	0.03[-0.64,0.69]
Total ***	**368**		**317**			**100%**	**-0.13[-0.28,0.02]**
Heterogeneity: Tau^2=0; Chi^2=1.1, df=4(P=0.89); I^2=0%							
Test for overall effect: Z=1.71(P=0.09)							



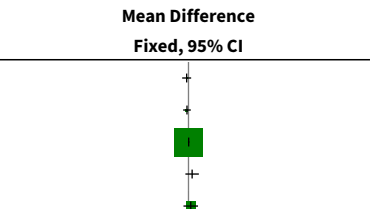
Analysis 1.4. Comparison 1 Therapy versus control (post-treatment), Outcome 4 Migraine medication usage.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Fritsche 2010	60	4.3 (2.8)	55	5 (3.1)		37.66%	-0.25[-0.62,0.12]
Kleiboer 2014	195	2.6 (3.5)	173	2.4 (2.8)		62.34%	0.06[-0.14,0.27]
Total ***	**255**		**228**			**100%**	**-0.06[-0.35,0.24]**
Heterogeneity: Tau^2=0.03; Chi^2=2.13, df=1(P=0.14); I^2=53.07%							
Test for overall effect: Z=0.36(P=0.72)							



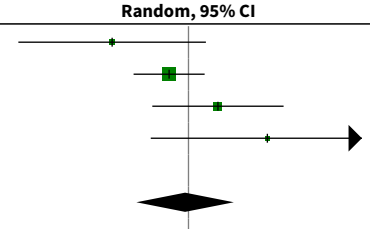
Analysis 1.5. Comparison 1 Therapy versus control (post-treatment), Outcome 5 Mood.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Bromberg 2012	94	20.4 (9.4)	95	21.4 (8.8)		2.47%	-1.05[-3.64,1.54]
Cousins 2015	27	5.6 (4.7)	28	6.4 (3.5)		3.42%	-0.87[-3.07,1.33]
Fritsche 2010	60	4.7 (1.2)	57	4.5 (1.2)		92.07%	0.11[-0.31,0.53]
Hedborg 2011	23	8.9 (6.5)	13	6.8 (5.2)		1.1%	2.1[-1.78,5.98]
Hedborg 2011	23	8.1 (7.3)	12	6.8 (5.2)		0.94%	1.3[-2.89,5.49]
Total ***	**227**		**205**			**100%**	**0.08[-0.33,0.49]**
Heterogeneity: Tau^2=0; Chi^2=2.83, df=4(P=0.59); I^2=0%							
Test for overall effect: Z=0.39(P=0.7)							



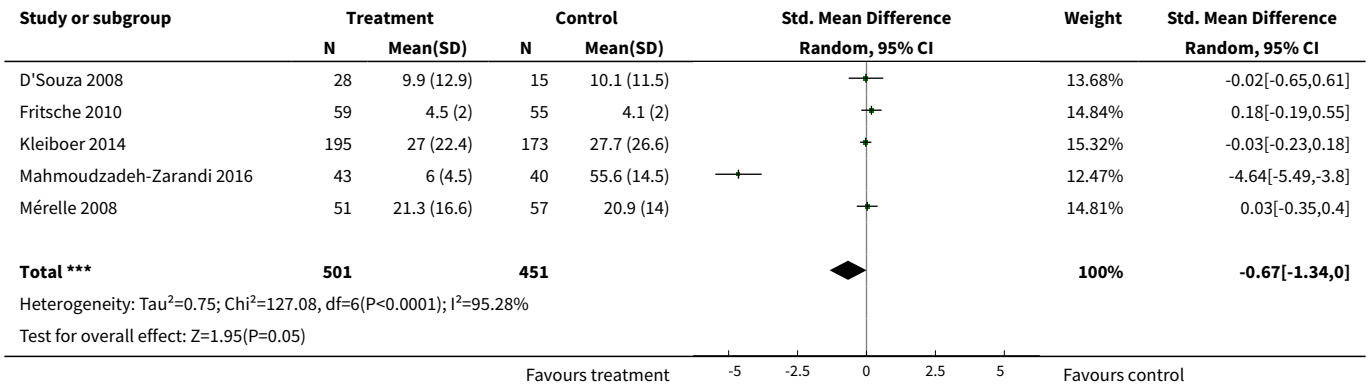
Analysis 1.6. Comparison 1 Therapy versus control (post-treatment), Outcome 6 Quality of life.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Cousins 2015	26	0.7 (0.3)	28	0.8 (0.2)		17.96%	-0.44[-0.98,0.1]
Kleiboer 2014	195	53 (7.8)	173	53.9 (8.3)		41.7%	-0.11[-0.32,0.09]
Mérelle 2008	51	58.2 (7.2)	57	56.8 (8.9)		27.17%	0.17[-0.21,0.55]
Rashid-Tavalai 2016	18	61.7 (10.9)	17	56.9 (9.6)		13.17%	0.45[-0.22,1.13]
Total ***	**290**		**275**			**100%**	**-0.02[-0.3,0.26]**
Heterogeneity: Tau^2=0.04; Chi^2=5.81, df=3(P=0.12); I^2=48.37%							
Test for overall effect: Z=0.14(P=0.89)							

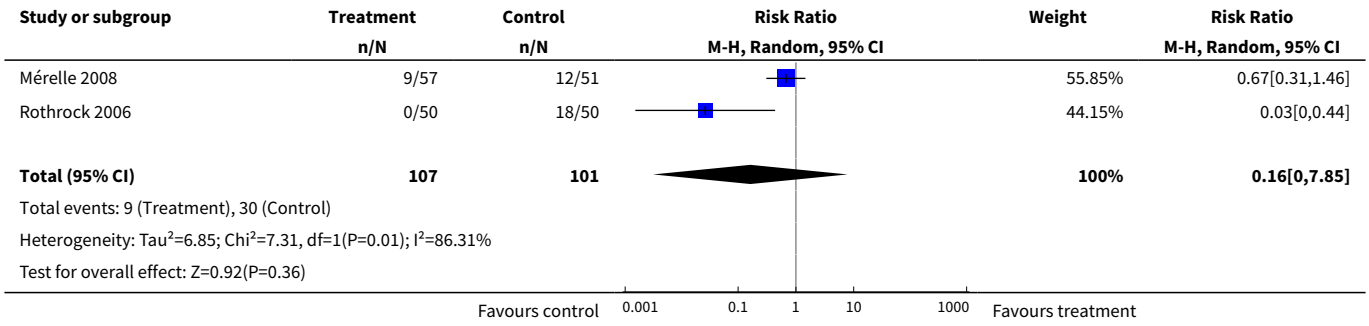


Analysis 1.7. Comparison 1 Therapy versus control (post-treatment), Outcome 7 Migraine-related disability.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Bromberg 2012	94	42.5 (5.1)	95	46 (4.8)		15.09%	-0.72[-1.01,-0.42]
D'Souza 2008	31	9.9 (8.8)	16	10.1 (11.5)		13.8%	-0.03[-0.63,0.58]



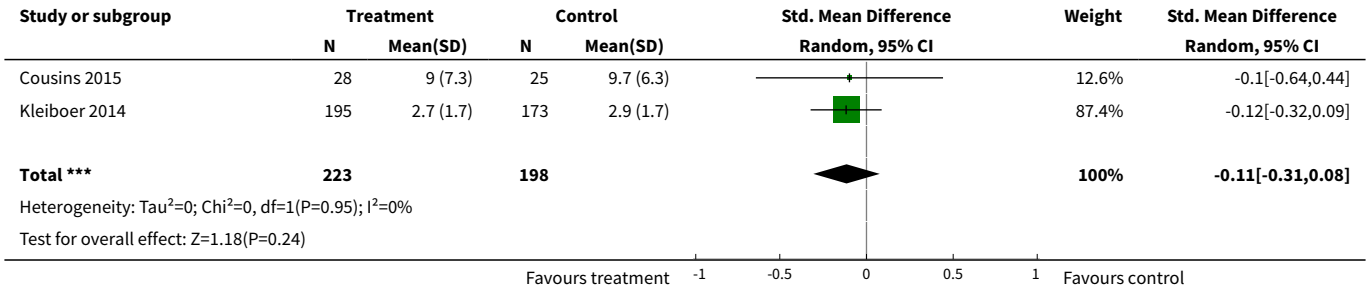
Analysis 1.8. Comparison 1 Therapy versus control (post-treatment), Outcome 8 Adverse events.



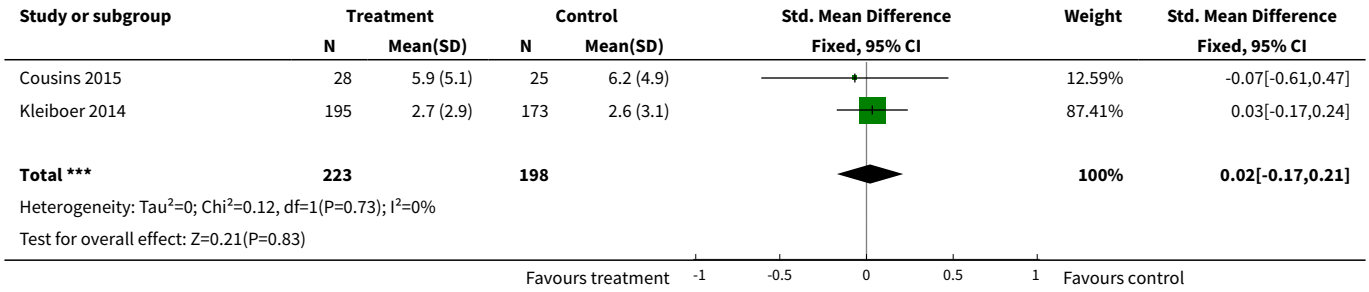
Comparison 2. Therapy versus control (follow-up)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Reduction in migraine frequency:	2	421	Std. Mean Difference (IV, Random, 95% CI)	-0.11 [-0.31, 0.08]
2 Migraine medication usage	2	421	Std. Mean Difference (IV, Fixed, 95% CI)	0.02 [-0.17, 0.21]
3 Mood	3	247	Std. Mean Difference (IV, Random, 95% CI)	-0.08 [-0.35, 0.18]
4 Quality of life	2	424	Std. Mean Difference (IV, Random, 95% CI)	0.13 [-0.07, 0.32]
5 Migraine-related disability	3	544	Std. Mean Difference (IV, Random, 95% CI)	-0.04 [-0.21, 0.13]

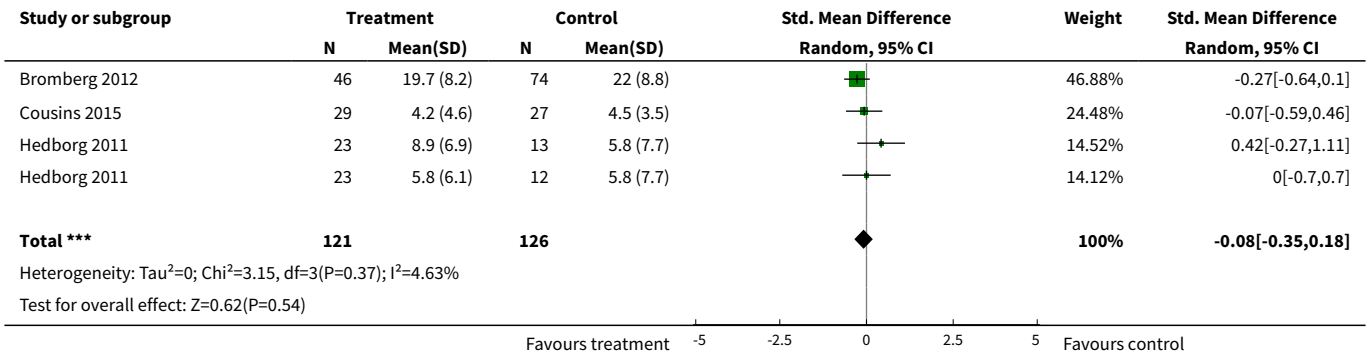
Analysis 2.1. Comparison 2 Therapy versus control (follow-up), Outcome 1 Reduction in migraine frequency:.



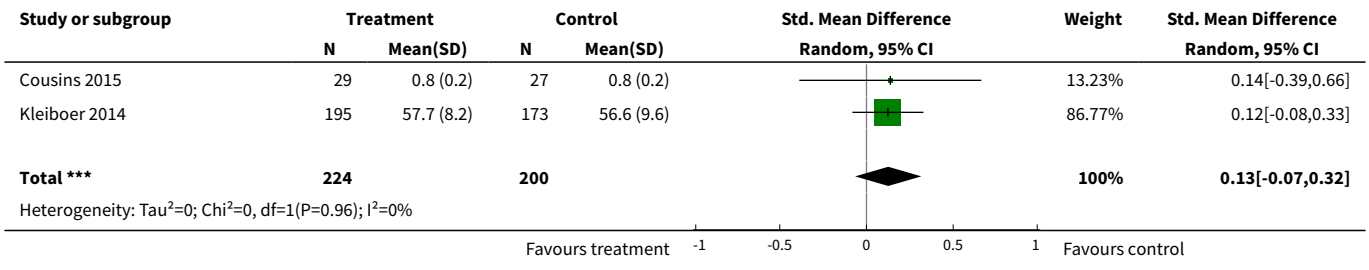
Analysis 2.2. Comparison 2 Therapy versus control (follow-up), Outcome 2 Migraine medication usage.



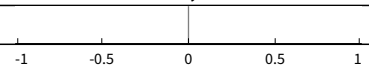
Analysis 2.3. Comparison 2 Therapy versus control (follow-up), Outcome 3 Mood.



Analysis 2.4. Comparison 2 Therapy versus control (follow-up), Outcome 4 Quality of life.

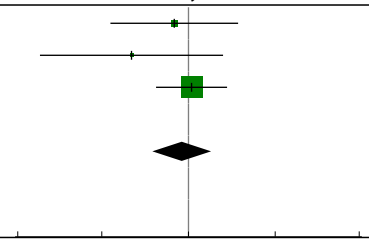


Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Test for overall effect: Z=1.29(P=0.2)							



Analysis 2.5. Comparison 2 Therapy versus control (follow-up), Outcome 5 Migraine-related disability.

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Std. Mean Difference Random, 95% CI	Weight	Std. Mean Difference Random, 95% CI
Bromberg 2012	46	36.1 (39)	74	39.5 (42.5)		21.18%	-0.08[-0.45,0.29]
Cousins 2015	29	33.9 (34.9)	27	53.9 (78.5)		10.3%	-0.33[-0.86,0.2]
Kleiboer 2014	195	27.1 (30.2)	173	26.6 (25.5)		68.51%	0.02[-0.19,0.22]
Total ***	**270**		**274**			**100%**	**-0.04[-0.21,0.13]**
Heterogeneity: Tau^2=0; Chi^2=1.5, df=2(P=0.47); I^2=0%							
Test for overall effect: Z=0.45(P=0.65)							



ADDITIONAL TABLES

Table 1. Treatment type, duration and setting

Study	Treatment type	Treatment duration	Treatment setting
Bhombal 2014	Behavioural	2 sessions	Clinic/home
Bromberg 2012	CBT	8 x 20-minute sessions	Home
Calhoun 2007	Behavioural	1 x 20-minute session	Clinic
Cousins 2015	CBT	3 sessions; 2 phone calls	Clinic/home
D'Souza 2008	Written emotional discourse Relaxation	4 sessions	Clinic
Feuille 2015	Mindfulness	1 session	Clinic/home
Fritsche 2010	CBT	5 x 2-hour sessions	Clinic
Hedborg 2011	Behavioural	Not reported	Home
Holroyd 2010	Behavioural	4 sessions	Clinic
Kang 2009	Biofeedback	8 sessions	Clinic
Kaushik 2005	Biofeedback + relaxation	10 sessions	Clinic/home
Kleiboer 2014	Behavioural	8 online lessons x 1 hour	Home

Table 1. Treatment type, duration and setting *(Continued)*

Kohlenberg 1981	CBT + biofeedback	10 weeks maximum	Home
Mahmoudzadeh-Zarandi 2016	Behavioural	4 x 30-45-minute sessions	Clinic
Marcus 2008	EMDR	1 session	Clinic
Mérelle 2008	Behavioural	7 x 2-hour sessions	Home
Meyer 2016	Relaxation	6 sessions	Clinic
Rashid-Tavalai 2016	CBT	7 x 2-hour sessions	Clinic
Richardson 1989	CBT	8 weeks	Clinic/home
Rothrock 2006	Psychoeducation	3 x 90-minute sessions	Clinic
Sargent 1986	Biofeedback	22 x 20-minute sessions	Clinic

CBT: cognitive behavioural therapy; **EMDR:** eye movement desensitisation and reprocessing

APPENDICES

Appendix 1. Search strategies

CENTRAL (CRSO)

#1 MESH DESCRIPTOR Psychotherapy EXPLODE ALL TREES

#2 psychotherap*:TI,AB,KY

#3 ((psycho* adj3 therap*)):TI,AB,KY

#4 MESH DESCRIPTOR Counseling EXPLODE ALL TREES

#5 counsel*:TI,AB,KY

#6 MESH DESCRIPTOR Behavior Therapy EXPLODE ALL TREES

#7 (relaxation or imagery or (behavio#r adj3 therap*))

#8 (biofeedback or (stress adj2 manag*))

#9 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8

#10 MESH DESCRIPTOR Migraine Disorders EXPLODE ALL TREES

#11 ((migrain* or (sick adj1 headache*))):TI,AB,KY

#12 #10 OR #11

#13 #9 AND #12

MEDLINE (OVID)

1 exp Psychotherapy/

2 psychotherap*.tw.

3 (psycho* adj3 therap*).tw.

4 Counseling/

5 counsel*.tw.

6 exp Behavior Therapy/

7 (relaxation or imagery or (behavio#r adj3 therap*)).tw.

8 biofeedback.tw.

9 (stress adj2 manag*).tw

10 or/1-9

11 exp Migraine Disorders/

12 (migrain* or (sick adj1 headache*)).tw.

13 11 or 12

14 10 and 13

15 randomized controlled trial.pt.

16 controlled clinical trial.pt.

17 randomized.ab.

18 placebo.ab.

19 drug therapy.fs.

20 randomly.ab.

21 trial.ab.

22 groups.ab.

23 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22

24 exp animals/ not humans.sh.

25 23 not 24

26 14 and 25

Embase (OVID)

1. exp Psychotherapy/
2. psychotherap*.tw.
3. (psycho* adj3 therap*).tw.
4. Counseling/
5. counsel*.tw.
6. exp Behavior Therapy/
7. (relaxation or imagery or (behavio#r adj3 therap*)).tw.
8. (biofeedback or (stress adj2 manag*)).tw.
9. or/1-8
10. exp Migraine/
11. (migrain* or (sick adj1 headache*)).tw.
12. 10 or 11
13. 9 and 12
14. random$.tw.
15. factorial$.tw.
16. crossover$.tw.
17. cross over$.tw.
18. cross-over$.tw.
19. placebo$.tw.

20. (doubl$ adj blind$).tw.
21. (singl$ adj blind$).tw.
22. assign$.tw.
23. allocat$.tw.
24. volunteer$.tw.
25. Crossover Procedure/
26. double-blind procedure.tw.
27. Randomized Controlled Trial/
28. Single Blind Procedure/
29. or/14-28
30. (animal/ or nonhuman/) not human/
31. 29 not 30
32. 13 and 31

PsycINFO (OVID)

1. exp Psychotherapy/
2. psychotherap*.tw.
3. (psycho* adj3 therap*).tw.
4. Counseling/
5. counsel*.tw.
6. exp Behavior Therapy/
7. (relaxation or imagery or (behavio#r adj3 therap*)).tw.
8. (biofeedback or (stress adj2 manag*)).tw.
9. or/1-8
10. Migraine Headache/
11. (migrain* or (sick adj1 headache*)).tw.
12. 10 or 11
13. 9 and 12
14. clinical trials/
15. (randomis* or randomiz*).tw.
16. (random$ adj3 (allocat$ or assign$)).tw.
17. ((clinic$ or control$) adj trial$).tw.
18. ((singl$ or doubl$ or trebl$ or tripl$) adj3 (blind$ or mask$)).tw.
19. (crossover$ or "cross over$").tw.
20. random sampling/
21. Experiment Controls/
22. Placebo/
23. placebo$.tw.
24. exp program evaluation/
25. treatment effectiveness evaluation/
26. ((effectiveness or evaluat$) adj3 (stud$ or research$)).tw.
27. or/14-26
28. 13 and 27

CINAHL (EBSCO)

S23 S13 AND S22
S22 S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21
S21 (allocat* random*)
S20 (MH "Quantitative Studies")
S19 (MH "Placebos")
S18 placebo*
S17 (random* allocat*)
S16 (MH "Random Assignment") S
S15 (Randomi?ed control* trial*)
S14 (singl* blind*) or (doubl* blind*) or (tripl* blind*) or (trebl* blind*) or (trebl* mask*) or (tripl* mask*) or (doubl* mask*) or (singl* mask*)
S13 S9 AND S12
S12 S10 OR S11
S11 (migrain* or (sick N1 headache*))
S9 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8
S8 (biofeedback or (stress N2 manag*))

S7 (relaxation or imagery or (behavio#r N3 therap*))
S6 (MH "Behavior Therapy+")
S5 counsel*
S4 (MH "Counseling")
S3 (psycho* N3 therap*)
S2 psychotherap*
S1 (MH "Psychotherapy+")

WHAT'S NEW

Date	Event	Description
2 July 2019	Review declared as stable	See Published notes.

CONTRIBUTIONS OF AUTHORS

LS, IM, and BM developed the concept for this review. LS led the delivery of the review, oversaw the review process and is responsible for future updates of this review. LS and JD selected studies for inclusion, extracted data, assessed risk of bias, and analysed data. LS, JD, AW, MN, IM, AB, MW and BM all contributed to the final authoring of the review.

DECLARATIONS OF INTEREST

LS: none known. LS is a clinical psychologist and practices cognitive behavioural therapy (CBT) with patients with a range of chronic health problems.

JD: none known

AW: none known. AW is a clinical psychologist involved in designing services for chronic pain including migraine.

MN: is a clinical psychologist involved in designing services for chronic pain including migraine. MN co-authored the book, *Manage Your Pain*, and receives royalties. MN has stocks in Medibank Private.

IM: none known

AB: none known. AB is a clinical psychologist and practices CBT for patients with a range of mental health problems.

MW: none known

BM: none known. BM is a clinical psychologist and practices CBT for patients with headache and chronic pain.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We adhered closely to the protocol, but in order to have sufficient data to analyse the primary and some of the secondary outcomes quantitatively, we accepted any measures based on headache diaries that had been recorded for at least seven consecutive days rather than the four weeks that had been nominated a priori. For migraine frequency, all of those that provided usable data did use a four-week diary, but half used the number of migraine attacks (n = 2) and half the number of migraine days (n = 2). Since these outcomes are highly related, and both are a legitimate measure of migraine frequency, we combined them to assess outcomes on migraine frequency. For the primary analysis, all studies used a four-week time period. We planned a number of moderator analyses as part of our protocol, but did not have sufficient data to provide analyses of these variables. In addition, studies used a range of follow-ups and time points for outcomes. We included the first outcome as the measure for post-treatment; and the final outcome reported as the measure for follow-up.

We revised our GRADE approach in line with current standards, and added detail regarding how these decisions were made, including substantial downgrading for inadequate study quality and size.

We adhered consistently to the protocol in other respects.

NOTES

This review was published in July 2019 with the results of the latest search fully incorporated. The editors and authors judge that it is unlikely that new evidence with the potential to change the conclusions will be published before 2024. Therefore, this review has been

stabilised until 2024 when it will be assessed for updating. If appropriate, we will update the review sooner if new evidence likely to change the conclusions is published, or if standards change substantially which necessitate major revisions.

INDEX TERMS

Medical Subject Headings (MeSH)

Anxiety [therapy]; Cognitive Behavioral Therapy; Depression [therapy]; Migraine Disorders [*prevention & control]; Psychotherapy [*methods]; Quality of Life; Randomized Controlled Trials as Topic

MeSH check words

Humans